National Institutes of Health

Part I

Evaluation Plan

FY 1982

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES
Public Health Service
National Institutes of Health
Bethesda, MD 20205

REF

NATIONAL INSTITUTES OF HEALTH

EVALUATION PLAN

FY 1982

Part I

Evaluation Program Strategy Statements
Abstracts of Proposed Projects
Plans for Program Performance Evaluation
Impact Statements

October 1981

Prepared by the
Office of Program Planning and Evaluation
National Institutes of Health

For Administrative Use

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service National Institutes of Health

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FOREWORD

This Evaluation Plan, the third in a series, is an outgrowth of enhanced planning and evaluation processes at the National Institutes of Health.

The Office of the Associate Director for Program Planning and Evaluation is responsible for the conduct of the NIH Evaluation Program, which includes formal evaluation studies supported out of a special Departmental fund--the so-called "one percent set-aside." This fund came into existence with the amendment of the Public Health Service Act in 1970. Section 513 established a tap of up to one percent of the funds appropriated to any program authorized by the PHS Act or several related acts. The legislation provides that the funds are to be used at the discretion of the Secretary for the evaluation of health programs. The Secretary subsequently delegated responsibility for releasing funds and coordinating evaluation planning to the Assistant Secretary for Planning and Evaluation. In accordance with the legislative intent, the evaluation of HHS health programs is carried out as part of an annual evaluation plan approved by the Assistant Secretary.

Program evaluation, like planning, is decentralized. Each Institute is responsible for developing its own program of studies, but is offered guidance and consultative assistance by the Office of Program Planning and Evaluation. This office has both administrative and research responsibilities in the area of evaluation. It recommends evaluation program policy to the Director, NIH, manages evaluation procedures for NIH as a whole, directs and carries out cross-cutting studies of NIH-wide evaluation issues, and provides leadership in the development of evaluation methods.

In preparing their FY 1982 evaluation plans, NIH Institutes have followed a three-stage approach recommended by the Department:

- Clarification of program goals and identification of program objectives and performance indicators, in terms of which program performance would be assessed;

- Development of agreed-upon evaluation designs or other information systems; and

- Production of program performance information in terms of agreed-upon evaluation design or some other information system.

The NIH Evaluation Plan reflects continued attention to enhancement of the evaluation program and its integration with planning. An Evaluation Oversight Committee, chaired by the Associate Director for Program Planning and Evaluation, has been working over the past year to coordinate these efforts. This Committee reviewed all aspects of NIH program evaluation and considered recommendations for further development and changes. The Committee completed a review of the program performance summary concept, and recommended that such summaries provide the principal documentation for consideration of individual programs in the Director's spring and fall review sessions. The Department's program performance guidance was reshaped to make it serve for program review purposes and provide a bridge to the Department's evaluation requirements for NIH. In addition, as part of the planning and evaluation process during FY 1982, NIH will begin to develop summaries for those programs, such as research training, that cut across NIH Institutes. Thus, the NIH planning document will include program performance summaries as a regular feature, and will be cross-referenced to the Evaluation Plan.

Another set of issues addressed by the Evaluation Oversight Committee concerned the reporting of evaluation projects and subsequent report use. A shift from past emphasis of program administration and evaluation plan development has permitted focus on evaluation results and their use in relation to planning, legislation, budget, and evaluation issues generally. It was agreed that "impact" statements requested by the Department are potentially the most useful means of disseminating information about the utilization of evaluation project results. Thus, in February, Institutes were requested to develop impact statements for all evaluation projects that have been completed during the previous four years. Approximately 50 statements are being published for the first time in the NIH Evaluation Plan for FY 1982.

The planning and evaluation documents should provide an excellent framework for general consideration of NIH policy, program evaluation, budget, and legislative concerns. They should also prove useful to the Public Health Service, the Department, the OMB, the Congress, the greater scientific community, and the general public. During the coming year, the integration of planning and evaluation activities will continue to receive close attention.

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INTRODUCTION AND SCHEDULE OF PROGRAM PERFORMANCE EVALUATIONS

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INTRODUCTION

The NIH FY 1982 Evaluation Plan is presented in two volumes. Part I outlines the evaluation program strategy of the Office of the Director and of each of the NIH Bureaus, Institutes, and Divisions (BIDs). These presentations are followed by "impact statements," which describe the results, recommendations, and effects on programs of some completed evaluations.

Part II contains descriptive outlines of projects proposed for funding in FY 1982 and summary descriptions of ongoing and recently completed evaluation projects. Lists of titles and budgets for all current evaluation activities, including proposed projects, are provided in both volumes for handy reference.

Not all of the proposals in Part II had yet been fully approved for funding from the evaluation set-aside as of October 1, 1981. Supplementary information and appeals, as well as new project proposals, may be (and are) submitted to the Department throughout the fiscal year. Information about the approval and implementation status of evaluation projects can be obtained from the National Institutes of Health Program Evaluation Branch, Building 1, Room 234, Bethesda, Md. 20205, or by telephone at (301) 496-4418.

Evaluation Strategy

The overall NIH evaluation strategy is guided by the Office of Program Planning and Evaluation, working in concert with evaluation program representatives from each of the BIDs. Section 3, in which the evaluation program of the Office of the Director is described, discusses the overall NIH evaluation program strategy and the role of the Office of the Director.

Characteristics of the FY 1982 Evaluation Program

The current activity status of the NIH evaluation program is outlined in Table 1. A substantial increase in the proportion of ongoing projects over last year reflects increasingly stringent budgets, which result for many projects in having to delay or stretch out the funding. Overall, the Department has raised fewer questions and objections to this year's evaluation plan. The proportion of projects in a less than fully approved status has been reduced from 30 percent in FY 1981 to 15 percent at the same time in FY 1982.

Table 2 summarizes the 1981 and 1982 evaluation programs in terms of type or approach. FY 1982 evaluation plans include substantial increases in planned or ongoing short-term and full-scale program evaluations. The proportion of the evaluation budget that will be spent on these evaluations of specific NIH programs will increase from 47 percent to 78 percent. No funds will be spent in FY 1982 on state-of-the-science reviews, and methodological investigations will use only one percent of the budget instead of the 18 percent invested in FY 1981. These trends exemplify NIH response to Departmental emphasis on program perfor-

mance evaluations as outlined in the FY 1981 Departmental Guidance for Program Evaluation. Schedules have deen developed for carrying out exploratory, short-term, and full-scale evaluations on all NIH programs, as listed in this section.

Table 1

Summary of the Number of Projects, Funding, and Percent Distribution by Project Status
FY 1982

(Set-Aside $ in Thousands)

Status	Number of Projects	Percent	FY 82 Cost Estimate	Percent
Ongoing Projects	72	60	$2,208	35
ASPE Approved - Not Yet Implemented	29	24	2,420	38
Conditionally Approved	9	8	980	16
Proposed Projects - Further Discussion Required	8	7	693	11
Disapproved by ASPE/ASH	1	1	--	--
Total, FY 1982	119	100	$6,301	100

Completed Projects: 20

Table 2

Distribution of Types of Evaluation Projects
FY 1981 and 1982

(Set-Aside $ in Thousands)

Type of Evaluation	FY 1981 Number	%	$	%	FY 1982 Number	%	$	%
Program Evaluation								
Evaluability Assessment	8	8	$ 332	10	11	9	$ 480	8
Short Term	9	10	4	0	16	14	1,155	18
Full Scale	25	27	1,174	37	39	33	3,281	52
Effectiveness	14	15	498	16	20	17	832	13
State of Science	9	10	187	6	3	3	0	0
Mechanisms	6	6	286	9	7	6	390	6
Methodology	10	11	590	18	12	10	68	1
Resource Development	12	13	139	4	10	8	95	2
Total	93	100	$3,210	100	118	100	$6,301	100

SCHEDULE FOR NIH PROGRAM PERFORMANCE EVALUATIONS

Institute / Program /Subprogram Name	PROGRAM PERFORMANCE EVALUATION ACTIVITIES				
	Stage 1		Stage 2		Stage 3
	Clarification of Program Goals, Objectives, etc.		Agreement on Eval. Design or Information Syst.		Production of Program Performance Information
	Begin Date	Compltn. Date	Begin Date	Compltn. Date	Availability Date
NCI					
Tumor Biology Research	7/81	12/81	12/81	2/82	NYD
Immunology Research	6/81	11/81	11/81	1/82	NYD
Epidemiology Research	6/81	12/81	12/81	2/82	NYD
Chemical & Physical Carcinogenesis Research	7/81	12/81	12/81	3/82	NYD
Biological Carcinogenesis Research	6/81	11/81	11/81	2/82	NYD
Nutrition Research	8/81	2/82	2/82	5/82	NYD
Diagnosis Research	7/81	1/82	1/82	4/82	NYD
Preclinical Treatment Research	7/81	12/81	12/81	2/82	NYD
Clinical Treatment Research	6/81	11/81	11/81	1/82	NYD
Rehabilitation Research	7/81	1/82	1/82	3/82	NYD
Cancer Control	7/81	1/82	1/82	4/82	NYD
Manpower Development	5/81	11/81	11/81	1/82	NYD
Construction	6/81	11/81	11/81	1/82	NYD
Centers	8/81	2/82	2/82	5/82	NYD
Communications/ Information	7/81	11/81	11/81	1/82	NYD

SCHEDULE FOR NIH PROGRAM PERFORMANCE EVALUATIONS

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	Stage 1 Clarification of Program Goals, Objectives, etc.		Stage 2 Agreement on Eval. Design or Information Syst.		Stage 3 Production of Program Performance Information
	Begin Date	Compltn. Date	Begin Date	Compltn. Date	Availability Date
NHLBI					
Heart and Vascular Diseases					
Arteriosclerosis	1/81	8/81	3/81	11/81	8/82
Hypertension	"	"	"	"	"
Cerebrovascular Diseases	"	"	"	"	"
Coronary Heart Disease	"	"	"	"	"
Peripheral Vascular Dis.	"	"	"	"	"
Arrhythmias	"	"	"	"	"
Heart Failure & Shock	"	"	"	"	"
Congenital & Rheumatic Heart Diseases	"	"	"	"	"
Cardiomyopathies & Infections of the Heart	"	"	"	"	"
Circulatory Assistance	"	"	"	"	"
Lung Diseases					
Structure & Function of the Lung	"	"	"	"	"
Emphysema and Chronic Bronchitis	"	"	"	"	"
Pediatric & Pulmonary Diseases	"	"	"	"	"
Fibrotic & Immunologic Lung Diseases	"	"	"	"	"
Respiratory Failure	"	"	"	"	"
Pulmonary Vascular Diseases	"	"	"	"	"
Blood Diseases and Resources					
Bleeding & Clotting Disorders	"	"	"	"	"
Disorders of the Red Blood Cell	"	"	"	"	"
Sickle Cell Disease	"	"	"	"	"
Blood Resources	"	"	"	"	"

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	Begin Date	Completn. Date	Begin Date	Completn. Date	Availability Date
NEI					
Retinal & Choroidal Diseases	10/79	12/80	4/80	6/81	4/82
Corneal Diseases	10/79	12/80	4/80	6/81	4/82
Cataract	10/79	12/80	4/80	6/81	4/82
Glaucoma	10/79	12/80	4/80	6/81	4/82
Sensory and Motor Disorders of Vision	10/79	12/80	4/80	6/81	4/82
NIA					
National Institute on Aging	5/82	12/82	12/82	9/83	9/84
NIAID					
Immunology, Allergic and Immunologic Diseases	9/81	9/82	--	--	--
Microbiology and Infectious Diseases	9/81	9/82	--	--	--
Evaluation of Institutional Biosafety Committee	6/80	6/81	6/81	6/82	6/83
Evaluation of NIAID Vaccine Development Program	3/81	6/81	6/81	12/81	6/84

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	Begin Date	Compltn. Date	Begin Date	Compltn. Date	Availability Date
NIADDK					
Arthritis, Musculoskeletal and Skin Diseases Program	12/82	9/83	--	--	--
Musculoskeletal Diseases program	8/81	8/83	8/81	8/83	8/84
Evaluation of the Needs and Priorities of Dermatologic Research	5/78	7/78	8/78	10/78	10/79
Diabetes, Endocrinology, and Metabolic Diseases Program	9/82	6/83	--	--	--
National Diabetes Information Clearing House	8/81	2/82	--	--	--
Evaluation of Research Needs in Endocrinology and Metabolic Diseases	5/78	7/78	8/78	10/78	11/79
Kidney Urology and Blood Diseases Program	NYD	NYD	--	--	--
Specialized Centers of Research in Urolithiasis	8/81	10/83	8/81	10/83	10/84
Evaluation of Research Needs in Nephrology and Urology	6/74	2/75	4/75	8/75	3/77
Evaluation of the Specialized Centers of Research (SCORs) in Urolithiasis in Relation to Program Goals	2/82	3/83	9/83	9/84	3/86
Digestive Diseases and Nutrition Program	6/83	3/84	--	--	--

SCHEDULE FOR NIH PROGRAM PERFORMANCE EVALUATIONS

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	Begin Date	Compltn. Date	Begin Date	Compltn. Date	Availability Date
NICHD					
Sudden Infant Death Syndrome	2/80	10/81	12/81	5/82	6/83
Child and Adolescent Development	2/80	10/81	12/81	5/82	6/83
Population Dynamics	2/80	10/81	12/81	5/82	6/83
Contraceptive Development	2/80	10/81	11/82	4/83	5/84
Congenital Defects	2/80	10/81	11/82	4/83	5/84
Fertility/Infertility	2/80	10/81	11/82	4/83	5/84
Pregnancy, Birth and the Infant	2/80	10/81	10/83	3/84	4/85
Nutrition	2/80	10/81	10/83	3/84	4/85
Contraceptive Evaluation	2/80	10/81	10/83	3/84	4/85
Mental Retardation	2/80	10/81	10/84	3/85	4/86
Intramural Research	10/81	9/82	10/82	9/83	10/84
Office of the Director	10/82	9/83	10/83	9/84	10/85
NIDR					
Periodontal Diseases	2/75	6/75	7/75	12/76	12/76
Caries	6/77	1/79	9/76	6/78	12/79
Craniofacial Anomalies	1/78	9/79	9/79	3/80	9/81
Restorative Materials	10/79	9/80	12/81*	4/82*	9/83*
Soft Tissue, Stomatology and Nutrition	12/79	11/80	9/82	1/83	6/84
Pain Control and Behavioral Studies	2/80	12/80*	9/83	1/84	6/85
Dental Research Institutes and Centers	4/80	5/80*	9/81	1/82	6/83

Note: * Date Revised

SCHEDULE FOR NIH PROGRAM PERFORMANCE EVALUATIONS

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	Begin Date	Compltn. Date	Begin Date	Compltn. Date	Availability Date
NIEHS					
Research Grants					
Individual Research Projects	NYD	---	---	---	---
Program Projects	NYD	---	---	---	---
NIEHS Centers					
Environmental Health Sciences Centers	/83	/84	/84	/84	/85
Marine and Freshwater Biomedical Centers	/85	/86	/86	/87	/87
Training and Manpower Development					
Toxicology	/79	/79	/79	/80	/81
Epidemiology and Biostatistics	/84	/85	/85	/86	/87
Mutagenesis	NYD	---	---	---	---
Veterinary Pathology	NYD	---	---	---	---
Research and Development Contracts	NYD	---	---	---	---

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	Begin Date	Compltn. Date	Begin Date	Compltn. Date	Availability Date
NIGMS					
Cellular and Molecular Basis of Disease					
Medical Scientist Training Program	/64	---	10/78	9/79	9/80
Genetics					
Program Performance	/71	---	6/80	8/80	9/81
Human Genetic Mutant Cell Repository	/71	---	7/81	7/83	NYD
Pharmacological Sciences	/73	---	9/82	NYD	NYD
Physiological Sciences					
NIGMS/OMAR Consensus Development Conference on Supportive Therapy	/78	---	5/80	10/81	11/81
Shared Instrumentation Initiative	/79	---	9/81	10/82	NYD
MARC Program					
MARC Faculty Fellowships	/72	---	1/79	1/81	10/81
MARC Honors Undergraduate	/77	---	9/82	NYD	NYD
NINCDS					
None					

SCHEDULE FOR NIH PROGRAM PERFORMANCE EVALUATIONS

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	Begin Date	Completn. Date	Begin Date	Completn. Date	Availability Date
NLM					
Regional Medical Libraries	6/80	9/80	9/80	4/81	9/82
Lister Hill Center	10/79	10/79	10/79	10/79	10/79
Library Operations	5/79	9/80	NYD	NYD	NYD
National Medical Audiovisual Center	1/81	NYD	NYD	NYD	NYD
Toxicology Information Program	*	*	*	*	*
Office of Computer and Communications Systems	4/79	6/79	6/79	9/79	12/80
NLM Medical Library Assistance Act					
Research Grants	7/77	1/78	NYD	NYD	NYD
Training Grants	6/80	9/80	9/80	1/81	5/81
Publication Grants	9/82	NYD	NYD	NYD	NYD
Special Scientific Project Grants	9/82	NYD	NYD	NYD	NYD
Resource Project Grants	12/79	9/79	NYD	NYD	NYD
Resource Improvement Grants	--/74	--/74	*	*	--/74

Note: * Performed as part of ongoing or completed activity. Exact dates unknown.

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FY 1982 NIH EVALUATION PROGRAM
RECENTLY COMPLETEO, ONGOING, ANO PROPOSEO PROJECTS

Summary Budget Table

Set Aside $ in Thousands; Institute Funds in ( )

BID	FY 81	FY 82	FY 83	Future Years
NCI	$ 66	$ 985	$ 463	$ ---
NHLBI	686 (41)	2,205	649	225
NEI	60 (5)	295	50	---
NIA	342	50	---	---
NIAID	--- (50)	55 (3)	28	---
NIAODK	336	450	80	---
NICHO	7	200	---	---
NIOR	9	300	375	---
NIEHS	46	---	---	---
NIGMS	--- (51)	100 (10)	---	---
NINCOS	317	170	150	---
ORR	---	300	---	---
NLM	--- (126)	195 (125)	145 (35)	---
BID TOTAL	2,027 (273)	5,305 (128)	1,940 (35)	225
OD NIH TOTAL	1,183	996	990	---
NIH TOTAL	$3,210 (273)	$6,301 (128)	$2,930 (35)	$ 225

Explanatory Notes And Codes:

Totals for prior years are only for the projects listed; they are not intended to summarize the program as a whole. Project start dates represent actual or estimated dates funds will be obligated and, if applicable, contract awarded. End dates represent time when final reports were, or will be available, ending the project. Institute supplied funds are enclosed in ( ) and treated as non-adds to set aside funds. NYO = Not Yet Determined (Code prior to contract award). Tr = Other office or agency.

Status Codes

A = Conditionally Approved/Deferred by ASH
A = Conditionally Approved/Oeferred by ASPE
B = Approved by ASPE
C = Deferred by NIH to Next Fiscal Year
D = ONGOING PROJECTS - Contract Awarded
D = Reports Available, Project Ongoing
E = COMPLETE PROJECTS
F = Project Complete But Reports and/or Summary Documentation Not Yet Available
G = Oropped by NIH
H = Modification or Extension Request Pending Approval
H = Resubmitted by NIH
H = PROPOSEO PROJECTS, approved by NIH
I = Disapproved by ASH or ASPE

Evaluation Type Codes

PE = Evaluability Assessment/Exploratory Eval.
PS = Short-Term Evaluations
PF = Full-Scale Evaluations
PP = Program Performance Summary
* = Study mandated by the Congress or Secretary HHS
EE = Effectiveness Evaluations
SS = State of the Science Evaluations
ME = Support Mechanism Evaluations
MO = Methodology Development
RD = Resource and Oata Development
M = Multiple Categories

Eval. Project No. / Project Title	Contract No.	Est./Actual Dates (Yr/Mo) Start	End	Status Code	SET-ASIDE FUND EXPENDITURES $ IN THOUSANDS Prior Years $	FY 81 $	FY 82 $	FY 83 $	Future Years $	PROJECT TOTAL $	Eval. Type
Office of the Director, NIH											
NIH 73-2 Evaluation of the Linkages Between Research Publication and NIH Funding	NO1-OD-1-2109	73/03	83/08	D	713	241	---	---	---	954	EE
NIH 74-2a Biomedical Scientist Employment Market	NO1-OD-5-2107	74/10	80/09	E	370	---	---	---	---	370	RD
NIH 75-1 NAS Continuing Study of National Needs for Biomedical and Behavioral Research Personnel	NO1-OO-9-2112	74/10	NYO	D	4,190	517	500	---	---	5,207	PF*
NIH 78-5 Evaluation of the Impact of Clinical Trials on Medical Practice	NO1-HV-8294	78/09	81/10	O	243	158	---	---	---	401	MO
NIH 79-302 Effectiveness of Computerized Medical Information System	NO1-CL-O-2117	80/06	81/12	D	165	24	---	---	---	189	PF
NIH 79-303 Analysis of Federally Sponsored Research in Low-Level Ionizing Radiation	NO1-CO-9-5466	79/07	81/10	O	863	73	---	---	---	936	SS*
NIH 80-301 Evaluation of the Consensus Development Process	NO1-OO-O-2131	80/01	83/09	D	567	---	---	---	---	567	MD
NIH 80-302 Evaluation of Technology Transfer in Patient Management	NO1-OO-O-2109	78/09	82/10	D	(12) 300	160	---	---	---	(12) 460	EE
NIH 80-304 IOM Study of Health-Related Effects of Marijuana Use and Abuse: A Research Agenda	NO1-OD-O-2114	80/09	81/12	D	340	114	---	---	---	454	SS*
NIH 80-305 Tr (NSF OA NAS 80-138) Assessment of Research Doctorate Programs: Development of an Evaluation Tool		80/06	82/03	D	50	---	---	---	---	50	RO
NIH 81-301 Evaluation of the Impact of RCOAs on the Recipients of These Awards	C-NYD	82/04	83/12	A	---	---	100	100	---	200	PF
NIH 81-302 Evaluation of the Present Strategy for the Dissemination of Consensus Development Statements	C-NYO	81/04	82/12	D	---	10	90	590	---	690	PE
NIH 81-303 Analysis of NIH Data Bases in Support of Program Evaluation	In house	80/10	82/09	O	---	2	23	---	---	25	PS
NIH 81-305 Evaluation of Planning at the National Institutes of Health	C-NYO	81/01	82/12	A	---	20	140	---	---	160	EE

Eval. Project No. / Project Title	Contract No.	Est./Actual Dates (Yr/Mo) Start	End	Status Code	SET-ASIDE FUND EXPENDITURES $ IN THOUSANDS Prior Years $	FY 81 $	FY 82 $	FY 83 $	Future Years $	PROJECT TOTAL $	Eval. Type
NIH 82-301 Effect of Stabilization of Research Grants on Academic and Nonacademic Biomedical Research Programs	C-NYD	81/11	83/10	A	---	---	30	200	---	230	PS
NIH 82-302 Evaluation of Research Manpower and Training Evaluation Activities	C-NYD	82/01	83/12	B	---	---	75	75	---	150	RD
NIH 82-303 A Method for Estimating MD Research Activity	C-NYD	81/10	81/12	H	---	---	18	---	---	18	MD
NIH 99-999 In house (DCRT)/Tr Evaluation Program Support Costs and Computer Services		79/06	82/09	D	8	22	20	25	---	75	RD
	00 NIH Total:				(12) $7,809	$1,183	$996	$990	$---	(12) $10,984	
National Cancer Institute											
NCI 77-2 Evaluation of the NCI Science Program Information System	NO1-CO-8-5414	78/09	80/09	F	(15) 150	---	---	---	---	(15) 150	EE
NCI 77-3 Evaluation of Regulations Affecting the Conduct of Clinical Cancer Research	NO1-CM-8-7173	78/09	81/01	F	294	---	---	---	---	294	EE
NCI/NHLBI 77-5 Health Education Message Testing System	NO1-CO-7-5360	77/09	81/10	D	172	66	---	---	---	238	MD
NCI 78-3 Evaluation of the Effectiveness of Cancer Education	NO1-CO-9-5464	79/09	81/10	D	200	---	---	---	---	200	EE
NCI 80-303 Evaluation of the Impact of Estrogen Receptor Assay on the Clinical Management of Patients with Breast Cancer	NO1-C8-04338	80/09	82/06	D	105	---	---	---	---	105	EE
NCI 80-304 Evaluation of Comprehensive Cancer Centers Communication Network	C-NYD	81/11	83/11	A	---	---	85	65	---	150	PF
NCI 81-301 Evaluation of Information Programs' Impact on Public Attitudes Towards Cancer	C-NYD	81/09	83/09	A	---	---	65	285	---	350	EE
NCI 82-301 Evaluation of the Supermarket Information Distribution System	C-NYD	NYO	NYD	H	---	---	(5) 80	---	---	(5) 80	EE

Eval. Project No. / Project Title	Contract No.	Est./Actual Dates (Yr/Mo) Start	End	Status Code	SET-ASIDE FUND EXPENDITURES $ IN THOUSANDS Prior Years $	FY 81 $	FY 82 $	FY 83 $	Future Years $	PROJECT TOTAL $	Eval. Type
NCI 82-302 Evaluation of Activities of the International Cancer Research Data Bank (ICRDB) Program	C-NYD	NYD	NYD	B		---	---	35	15	---	50	EE
NCI 82-303 Cancer Therapy Evaluation Program (CTEP) Information System	C-NYD	82/03	85/02	H	---	---	295	(98) 98	---	(98) 393	PF
NCI 82-304 Evaluation of Community Hospital Oncology Programs	C-NYD	NYD	NYC	B	---	---	300	---	---	300	PF
NCI 82-305 Evaluability Assessment of Cancer Control Programs for Clinical Cooperative Groups	Tr	81/09	NYD	B	---	---	125	---	---	125	PF
			NCI Total:		(15) $ 921	$ 66	(5) $ 985	(98) $ 463	$ ---	(118) $ 2,435	

National Heart, Lung and Blood Institute

NHLBI 77-4 Evaluation of Sickle Cell Education	NO1-HD-8-2935	78/09	81/06	F	150	---	---	---	---	150	PF
NHLBI/NCI 77-5 Health Education Message Testing System	NO1-CO-7-5360	77/09	81/10	D	167	66	---	---	---	233	MD
NHLBI 78-5 Evaluation of Progress in Pediatric Pulmonary Diseases	C-NYD	78/06	82/10	D	26	2	167	---	---	195	PS
NHLBI 78-6 Blood and Hypertension Research Manpower Data Base	In house/DCRT	78/06	81/10	D	118	5	---	---	---	123	MD
NHLBI 78-7 Evaluation of the Impact of Adenine on Blood Banking	NO1-HB-9-2911	79/06	82/06	D	270	75	95	---	---	440	PF
NHLBI 79-302 Evaluation of Health Hazard Appraisal in Work Setting Preventive Medicine Programs	NO1-HO-9-2934	79/09	81/10	D	308	---	---	---	---	308	PS
NHLBI 79-304 Evaluation of Sickle Cell Counseling	NO1-HB-1-3006	81/09	84/09	D	---	90	90	---	---	180	PF
NHLBI 79-309 Evaluation of Hyperlipoproteinemia Dietary Manuals and Physicians' Handbook	NO1-HO-0-2921	80/09	82/02	D	90	---	---	---	---	90	PF

Eval. Project No. / Project Title	Contract No.	Est./Actual Dates (Yr/Mo) Start	End	Status Code	SET-ASIDE FUND EXPENDITURES $ IN THOUSANDS Prior Years $	FY 81 $	FY 82 $	FY 83 $	Future Years $	PROJECT TOTAL $	Eval. Type
NHLBI 79-310 Evaluation of Pulmonary Academic Award Program	NO1-HR-0-2907	80/09	81/10	D	150	---	---	---	---	150	PF
NHLBI 79-311 Evaluation of Regimen Compliance in Long-Term Clinical Trials	NO1-HV-5-2901	79/06	81/12	D	155	---	25	---	---	180	ME
NHLBI 80-301 Pilot Evaluation of the SCOR Program (Formerly "Evaluability Assessment of the SCOR Mechanism")	C-NYD	81/07	82/06	D	---	---	130	---	---	130	PS
NHLBI 80-304 C-NYO/In house Evaluation of Statewide Hypertension Programs		80/06	82/06	O	18	38	124	---	---	180	PE
NHLBI 80-305 Evaluation of Compliance Improvement Program	In house	79/12	80/11	F	30	---	---	---	---	30	PS
NHLBI 80-306 Evaluation of the Effect of High Blood Pressure Media Messages on Health Professionals	NO1-HO-0-2924	80/10	81/10	D	28	---	---	---	---	28	MD
NHLBI 80-307 Evaluation of the Regional Training Workshops for Nutrition Counseling in Hyperlipidemia for Dietitians and Nutritionists	NO1-HV-02923	80/09	83/09	D	40	40	10	---	---	90	PF
NHLBI 80-308 Evaluation of the Sickle Cell Disease Health/Science Seminar	NO1-HB-1-3002/DCRT	81/05	83/05	D	---	63	55	47	---	165	PF
NHLBI 80-309 Evaluation of the DBDR Erythropoietin Program	263-79-C-0308	80/05	81/10	O	9	(41) ---	---	---	---	(41) 9	PF
NHLBI 80-310 Assessment of Reach and Frequency of High Blood Pressure Messages	C-NYD	81/03	84/03	D	---	---	102	54	---	156	EE
NHLBI 80-311 Evaluation of Methodology to Aggregate Clinical Trial Results	In house (DCRT)	80/05	81/10	D	9	---	---	---	---	9	MD
NHLBI/NIAID 81-303 Evaluation of Education Programs and Materials for Self-Management of Children with Asthma	In house/C-NYD	81/06	83/09	O	---	---	55	28	---	83	PS
NHLBI 81-304 Evaluation of Behavioral Medicine Program	In house	81/03	82/07	D	---	23	27	---	---	50	PE
NHLBI 81-306 Impact of Funding Decisions in the NHLBI Initiative Planning System	C-NYD	81/11	82/10	A	---	---	80	---	---	80	ME

Eval. Project No. / Project Title	Contract No.	Est./Actual Dates (Yr/Mo) Start	End	Status Code	SET-ASIDE FUND EXPENDITURES $ IN THOUSANDS Prior Years $	FY 81 $	FY 82 $	FY 83 $	Future Years $	PROJECT TOTAL $	Eval. Type
NHLBI 81-307 Evaluability Assessment of the Impact of the Hypertension Detection and Follow-Up Program	In house	81/02	82/10	0	---	37	83	---	---	120	PF
NHLBI 81-310 Impact of Anti-Smoking Policies on Smoking Activities in the Federal Government	N01-HO-1-3005	81/08	83/02	0	---	100	---	---	---	100	PF
NHLBI 81-312 Evaluation of the SCOR Program	C-NYD	82/09	84/08	A	---	---	---	150	---	150	PF
NHLBI 81-313 Tr (1-Y01-HV-10047-00) Evaluation of the Framingham & Other CHD Risk Models in a Large National Cohort		81/05	82/04	0	---	100	---	---	---	100	MD
NHLBI 81-314 Evaluation of Hypertension Control Demonstration: Phase I	In house	81/04	82/09	D	---	37	63	---	---	100	PF
NHLBI 81-315 Feasibility Assessment of a Program to Measure Changes in Causes of Death	Tr(Y01-HV-1-0008)	81/08	82/02	0	---	10	104	---	---	114	PE
NHLBI 81-316 Evaluation of Postdoctoral Research Training	In house	81/04	82/09	D	---	---	75	---	---	75	PS
NHLBI 82-301 Evaluation of the Impact of NHLBI-CDC Lipid Standardization Programs	C-NYD	NYD	NYD	H	---	---	---*	---	---	---	PE
NHLBI 82-302 Evaluation of the Impact of Coronary Primary Prevention Trial and the Multiple Risk Factor Intervention Trial: Baseline Measurements of Practice	C-NYD	NYD	NYO	B	---	---	300	50	---	350	PF
NHLBI 82-303 Interim Survey and Qualitative Research on Public Knowledge, Attitudes, and Behavior Regarding High Blood Pressure	C-NYD	81/11	82/06	B	---	---	50	---	---	50	PS
NHLBI 82-304 Evaluation of Primary Reference Material Program	C-NYD	81/10	84/09	B	---	---	40	30	40	110	EE
NHLBI 82-305 Impact of MRFIT Nutrition Education Programs on Blood Lipids and Nutritional Status	Tr(---)	81/09	82/09	H	---	---	100	50	---	150	ME
NHLBI 82-306 Evaluation of the Impact of Hypertension Detection and Followup Program (Phase II: Physician Practice)	C-NYD	NYD	NYD	B	---	---	150	150	---	300	PF

Eval. Project No. / Project Title	Contract No.	Est./Actual Dates (Yr/Mo) Start	End	Status Code	SET-ASIDE FUND EXPENDITURES $ IN THOUSANDS Prior Years $	FY 81 $	FY 82 $	FY 83 $	Future Years $	PROJECT TOTAL $	Eval. Type
NHLBI 82-307 The Impact of Research Support Reduction on Large Grant Supported Programs	C-NYD	NYD	NYD	H	---	---	80	---	---	80	PS
NHLBI 82-308 Evaluation of a Demonstration Program for Hypertension Control Using Community Health Centers (Phase II: Conduct of the Evaluation)	C-NYD	NYD	NYD	B	---	---	200	90	185	475	PF
			NHLBI Total:		$1,568	(41) $ 686	$2,205	$ 649	$ 225	(41) $ 5,333	

*To be submitted separately.

National Eye Institute

Eval. Project No. / Project Title	Contract No.	Est./Actual Dates (Yr/Mo) Start	End	Status Code	SET-ASIDE FUND EXPENDITURES $ IN THOUSANDS Prior Years $	FY 81 $	FY 82 $	FY 83 $	Future Years $	PROJECT TOTAL $	Eval. Type
NEI 80-301 Analysis of NEI Program Evaluation and Planning Process	In house	80/04	81/01	E	20	(5) ---	---	---	---	(5) 20	PS
NEI 80-306 Third Comprehensive NEI Program Evaluation and Plan	In house	79/10	81/12	D	60	60	60	---	---	180	PF
NEI 80-401 Tracking System for Implementation of Vision Research: A National Plan: 1978-1982 (subsumed within NEI 80-306)	In house	79/10	81/12	D	(15) ---	---	---	---	---	(15) ---	RD
NEI 80-404 Feasibility Study of Evaluation of NEI Core Centers	In house	80/04	81/10	D	(10) ---	---	---	---	---	(10) ---	PE
NEI 82-301 Design of a System for Evaluating the Implementation of the NEI 1983-87 Program Plan	C-NYD	82/02	83/01	B	---	---	100	---	---	100	PF
NEI 82-302 Evaluability Assessment of NEI Cataract Program	C-NYD	81/12	82/11	H	---	---	60	---	---	60	PE
NEI 82-303 Evaluation of NEI Program Analysis System	C-NYD	81/12	82/11	B	---	---	75	50	---	125	EE
			NEI Total:		(25) $ 80	(5) $ 60	$ 295	$ 50	$ ---	(30) $ 485	

Eval. Project No. / Project Title	Contract No.	Est./Actual Dates (Yr/Mo) Start	End	Status Code	SET-ASIDE FUND EXPENDITURES $ IN THOUSANDS Prior Years	FY 81	FY 82	FY 83	Future Years	PROJECT TOTAL	Eval. Type
					$	$	$	$	$	$	
National Institute on Aging											
NIA 79-301/3	NO1-AG-0-2104	80/06	82/06	O							PE
Evaluation of NIA Animal and Cellular Resources Programs					105	194	---	---	---	299	
NIA 79-302	NO1-AG-0-2130	80/09	82/09	D							RO
NIA Research Management Information System					157	117	---	---	---	274	
NIA 80-301	C-NYO	81/09	82/06	D							PF
Evaluation of the Geriatric Medicine Academic Award Program					---	31	---	---	---	31	
NIA 82-301	C-NYD	NYO	NYO	B							MD
Development of a Systematic Procedure for the Monitoring and Review of Research Grant Progress Reports					---	---	50	---	---	50	
			NIA Total:		$ 262	$ 342	$ 50	$ ---	$ ---	$ 654	
National Institute of Allergy and Infectious Diseases											
NIAID 79-401	NO1-A1-9-2600	78/11	81/03	F							RD
Evaluation of Microbiology Manpower					(102) ---	---	---	---	---	(102) ---	
NIAID 80-302 263-80-C-0530/In house		80/09	81/10	D							PF
Evaluation of Institutional Biosafety Committees (IBC)					(3) 147	---	---	---	---	(3) 147	
NIAIO 80-401	In house	80/01	82/12	D							EE
Evaluation of the Impact of the NIAIO OMAR Consensus Development Conference on Amantadine					(3) ---	---	(3) ---	---	---	(6) ---	
NIAIO/NHLBI 81-303 In house/C-NYO		81/06	83/09	O							PS
Evaluation of Educational Programs and Materials for Self-Management of Children with Asthma					(49) ---	---	55	28	---	(49) 83	
NIAID 82-301	C-NYO	81/07	85/02	I							PF
Evaluation of the NIAIO Vaccine Development Program					---	(50) ---	---	---	---	(50) ---	
			NIAIO Total:		(157) $ 147	(50) $ ---	(3) $ 55	$ 28	$---	(210) $ 230	

Eval. Project No. / Project Title	Contract No.	Est./Actual Dates (Yr/Mo) Start	End	Status Code	SET-ASIDE FUND EXPENDITURES $ IN THOUSANDS Prior Years	FY 81	FY 82	FY 83	Future Years	PROJECT TOTAL	Eval. Type
					$	$	$	$	$	$	
National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases											
NIAMDD 75-3 Evaluation of Research Alternatives to Minimize SSA/Medicare Costs for Dialysis Treatment	In house	75/05	80/08	E	45	---	---	---	---	45	SS
NIAMDD 77-1 Evaluation of Research Needs in Endocrinology and Metabolic Diseases	NO1-AM-7-2236	77/09	80/12	F	(153) 242	---	---	---	---	(153) 242	SS*
NIAMDD 77-3 Evaluation of Needs and Priorities in Dermatologic Research	NO1-AM-7-2215	77/07	80/07	E	(64) 250	---	---	---	---	(64) 250	SS*
NIAMDD 78-2 Evaluation of the Hematology Program of NIAMDD in Relation to Identification of Research Needs	NO1-AM-8-2219	78/09	81/10	D	175	---	---	---	---	175	SS
NIAMDD 79-303 Identification/Development of Methods for Evaluation of NIAMDD Center Grant Programs	NO1-AM-1-2202	81/06	82/06	D	---	135	---	---	---	135	MD*
NIAMDD 79-304 Evaluation of the Specialized Centers of Research (SCORs) in Urolithiasis in Relation to Program Goals	C-NYD	81/10	83/06	A	---	---	180	---	---	180	PF
NIAMDD 79-305 Identification of Methods for Evaluation of Non-Research Activities of Multipurpose Arthritis Centers	NO1-AM-1-2206	81/09	82/09	D	---	60	---	---	---	60	MD*
NIAMDD 80-301 Evaluation of the NIADDK Musculoskeletal Diseases Program	NO1-AM-1-2203	81/06	83/06	D	---	91	140	---	---	231	PF
NIAMDD 81-301 Evaluability Assessment of NIADDK National Diabetes Information Clearinghouse	Tr	81/06	82/02	D	---	50	---	---	---	50	PE
NIADDK 82-301 Utilization of Products Disseminated by the National Diabetes Information Clearinghouse	C-NYD	81/10	82/09	B	---	---	50	---	---	50	EE
NIADDK 82-302 Evaluation of Postdoctoral Research Training in the Diabetes, Endocrinology and Metabolic Diseases Program	C-NYD	82/07	84/06	B	---	---	80	80	---	160	PS
			NIADDK Total:		(217) $ 712	$ 336	$ 450	$ 80	$ ---	(217) $ 1,578	

Eval. Project No. / Project Title	Contract No.	Est./Actual Dates (Yr/Mo) Start	End	Status Code	SET-ASIDE FUND EXPENDITURES $ IN THOUSANDS Prior Years $	FY 81 $	FY 82 $	FY 83 $	Future Years $	PROJECT TOTAL $	Eval. Type
National Institute of Child Health and Human Development											
NICHO 80-305/6 Development of Objectives and Performance Indicators for NICHD Programs of Research	NO1-HO-0-2807	80/02	81/12	D	220	7	5	---	---	232	PE
NICHO 81-302 Stage 2 Evaluation of NICHO Sudden Infant Death Syndrome Research Program	C-NYO	81/12	82/05	C	---	---	20	---	---	20	PS
NICHO 81-304 Stage 1 Evaluation of NICHO Intramural Research Program	C-NYO	81/10	82/09	C	---	---	70	---	---	70	PE
NICHO 82-301 Evaluation of NICHD Research Resources Program	C-NYC	82/01	82/12	B	---	---	65	---	---	65	EE
NICHO 82-302 Stage 2 Evaluation of NICHO Child and Adolescent Development Research Program	C-NYD	81/12	82/05	B	---	---	20	---	---	20	PS
NICHO 82-303 Stage 2 Evaluation of NICHD Population Dynamics Research Program	C-NYO	81/12	82/05	B	---	---	20	---	---	20	PS
			NICHO Total:		$220	$ 7	$ 200	$ ---	$ ---	$ 427	
National Institute of Dental Research											
NIDR 77-8 263-80-C-0580/In house Evaluation of the NIOR Cranio-facial Anomalies Program		80/09	81/12	D	(30) 281	9	---	---	---	(30) 290	PF
NIDR 82-301 Assessment of Selected Activities Associated With Dental Research Centers	C-NYO	81/10	83/06	B	---	---	50	50	---	100	PS
NIOR 82-302 Evaluation of the NIDR Restorative Materials Research Activities	C-NYD	81/12	83/09	B	---	---	250	50	---	300	PF
NIDR 83-301 Evaluation of the NIDR Soft Tissue Stomatology and Nutrition Research Activities	C-NYO	82/09	84/06	B	---	---	---	275	---	275	PF
			NIDR Total:		(30) $ 281	$ 9	$ 300	$ 375	$ ---	(30) $ 965	

Eval. Project No. / Project Title	Contract No.	Est./Actual Dates (Yr/Mo) Start	End	Status Code	SET-ASIDE FUND EXPENDITURES $ IN THOUSANDS Prior Years	FY 81	FY 82	FY 83	Future Years	PROJECT TOTAL	Eval. Type
					$	$	$	$	$	$	
National Institute of Environmental Health Sciences											
NIEHS 79-301 Evaluation of the NIEHS Environmental Toxicology Training Program	NO1-ES-9-0005	79/06	81/11	D	202	46	---	---	---	248	ME
NIEHS 79-302 Analysis of Paraquat and its Degradation Products in Smoke for Paraquat Contaminated Marijuana	NO1-ES-9-0003	79/09	81/06	F	(48) 173	---	---	---	---	(48) 173	SS*
NIEHS 79-401 Tr(IR13-ES-01987-01) Program Planning Work Group		78/02	80/12	F	(61) ---	---	---	---	---	(61) ---	SS
			NIEHS Total:		(109) $ 375	$ 46	$---	$ ---	$ ---	(109) $421	
National Institute of General Medical Sciences											
NIGMS 79-401 Evaluation of Medical Scientist Training Program	In house	79/07	81/06	F	---	(5) ---	---	---	---	(5) ---	EE
NIGMS 80-401 Evaluation of the MARC Faculty Fellowship Program	In house	79/06	81/10	D	---	(5) ---	---	---	---	(5) ---	ME
NIGMS 80-402 Evaluation of Research Career Awardees	In house	80/03	81/03	F	---	(1) ---	---	---	---	(1) ---	ME
NIGMS 81-401 Survey of Genetic Activities	In house	80/10	81/10	D	---	(30) ---	---	---	---	(30) ---	RO
NIGMS 81-402 Evaluation of the Impact of the NIGMS/OMAR Consensus Development Conference on Supportive Therapy in Burn Care	In house	80/05	NYO	D	---	(10) ---	(5) ---	---	---	(15) ---	EE
NIGMS 82-301 Evaluation of Human Genetic Mutant Cell Repository	In house	82/07	83/06	B	---	---	100	---	---	100	PF
NIGMS 82-401 Evaluation of Shared Instrumentation Initiative	In house	81/09	82/10	B	---	---	(5) ---	---	---	(5) ---	EE
			NIGMS Total:		$---	(51) $ ---	(10) $ 100	$ ---	$ ---	(61) $ 100	

Eval. Project No. / Project Title	Contract No.	Est./Actual Dates (Yr/Mo) Start	End	Status Code	SET-ASIDE FUND EXPENDITURES $ IN THOUSANDS Prior Years	FY 81	FY 82	FY 83	Future Years	PROJECT TOTAL	Eval. Type
					$	$	$	$	$	$	
National Institute of Neurological and Communicative Disorders and Stroke											
NINCDS 74-1a Survey of the Incidence, Prevalence, and Cost of Intracranial Neoplasms	NO1-NS-4-2336	74/06	80/12	F	(488) 275	---	---	---	---	(488) 275	RD
NINCDS 74-1b Survey of the Incidence, Prevalence, and Cost of Stroke (Nation-wide study of Stroke)	NO1-NS-6-2333	75/07	80/12	F	(212) 374	---	---	---	---	(212) 374	RD
NINCDS 77-1 The National Hospital Survey of Disease (Formerly Comprehensive Disease Statistics Survey)	NO1-NS-7-2379	77/09	81/12	D	(772) 215	---	---	---	---	(772) 215	RD
NINCDS 77-3 Development and Test of Methods for Collection of Supplementary Survey Data for Determining Trends	NO1-NS-4-2334	76/10	81/04	F	41	---	---	---	---	41	RD
NINCDS 79-301 Evaluation of the Intramural Research Program	NO1-NS-1-2348	81/01	82/01	D	---	77	---	---	---	77	EC
NINCDS 80-302 Assessment of MEDLARS Services for Meeting the Information Transfer Needs in Communicative Disorders	Multi-contracts	80/09	83/02	D	242	240	110	---	---	592	ME
NINCDS 82-301 Evaluation of the Scientific Impact of Research Center/ Program Project Support and Individual Investigator Support in the Communicative Disorders Field	C-NYD	82/07	84/07	H	---	---	60	150	---	210	EE
			NINCDS Total:		(1,472) $ 1,147	$ 317	$ 170	$ 150	$ ---	(1,472) $ 1,784	
Division of Research Resources											
DRR 77-2 Evaluation of the Role of Clinical Research Centers in Clinical Trials with Emphasis on Information Processing	NO1-RR-8-2122	78/09	80/12	E	(92) 330	---	---	---	---	(92) 330	SS
DRR 82-301 Short-Term Evaluations of the Programs of the Division of Research Resources	C-NYD	82/03	82/07	A	---	---	300	---	---	300	PS
			DRR Total:		(92) $ 330	$ ---	$ 300	$ ---	$ ---	(92) $ 630	

Eval. Project No. / Project Title	Contract No.	Est./Actual Dates (Yr/Mo) Start	End	Status Code	SET-ASIDE FUND EXPENDITURES $ IN THOUSANDS Prior Years $	FY 81 $	FY 82 $	FY 83 $	Future Years $	PROJECT TOTAL $	Eval. Type
National Library of Medicine											
NLM 77-2a Regional Medical Library Program: Data Gathering	Multi-contracts	78/09	82/09	D	80	---	---	---	---	80	RD
NLM 77-2b Evaluation of the Regional Medical Library Program	NO1-LM-03538	80/09	81/10	D	100	---	---	---	---	100	PF
NLM 78-3 Evaluation of Information Transfer Program	NO1-LM-8-4733	78/09	81/06	F	(16) 108	---	---	---	---	(16) 108	EE
NLM 78-4 Evaluation of the NMAC Training Program	NO1-LM-8-4719	78/09	80/11	F	(23) 50	---	---	---	---	(23) 50	EE
NLM 79-302 Analysis of Requests of Inter-library Loans and Reader Services	In house	82/01	82/06	C	---	---	(5) ---	---	---	(5) ---	RD
NLM 79-303 Characteristics of AVLINE Use	C-NYD	NYD	NYD	B	---	---	70	70	---	140	EE
NLM 80-401 Evaluation of Medical Library Resource Project Grant Program	In house	79/11	NYD	D	---	(8) ---	---	---	---	(8) ---	ME
NLM 80-402 Consultant Review of Lister Hill Center Programs	In house	79/10	NYD	D	(4) ---	(10) ---	(10) ---	(10) ---	---	(34) ---	PF
NLM 80-403 Consultant Review of MEDLARS III	In house	79/05	NYD	D	(7) ---	(25) ---	(25) ---	(25) ---	---	(82) ---	PF
NLM 80-404 Medical Library Assistance Act Program Performance	In house	74/09	84/09	D	(16) ---	(8) ---	(NYD) ---	(NYD) ---	---	(24) ---	PF
NLM 80-405 National Medical Audiovisual Center Internal Program Evaluation	In house	80/03	82/12	D	(20) ---	(20) ---	(20) ---	---	---	(60) ---	PF
NLM 80-406 Computer Performance Measurement	In house	79/04	82/06	D	(100) ---	(50) ---	(50) ---	---	---	(200) ---	PF
NLM 81-401 Feedback Survey of NMAC's Film Video Cassette Loan Program Clients	In house	80/11	82/05	D	---	(5) ---	(5) ---	---	---	(10) ---	PF
NLM 82-301 On-line Services User Study	C-NYD	NYD	NYD	B	---	---	50	---	---	50	EE

Eval. Project No. / Project Title	Contract No.	Est./Actual Dates (Yr/Mo) Start	End	Status Code	SET-ASIDE FUND EXPENDITURES $ IN THOUSANDS Prior Years $	FY 81 $	FY 82 $	FY 83 $	Future Years $	PROJECT TOTAL $	Eval. Type
NLM 82-302 Evaluation of NLM's Services in the Behavioral Sciences	C-NYD	NYD	NYD	B	---	---	75	75	---	150	ME
NLM 82-401 Analysis of Use of NLM Cataloging Data	In house	NYD	NYD	B	---	---	(10) ---	---	---	(10) ---	RD
					(186)	(126)	(125)	(35)		(472)	
			NLM Total:		$ 338	$ ---	$ 195	$ 145	$ ---	$ 678	

3

OFFICE OF THE DIRECTOR, NIH

Dr. Thomas E. Malone, Acting Director

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Proposed Budget

		Dollars in Thousands FY 81	FY 82	FY 83
NIH 73-2	Evaluation of the Linkages Between Research Publication and NIH Funding	$ 241	$ ---	$ ---
NIH 75-1	NAS Continuing Study of National Needs for Biomedical and Behavioral Research Personnel	517	500	---
NIH 78-5	Evaluation of the Impact of Clinical Trials on Medical Practice	158	---	---
NIH 79-302	Effectiveness of Computerized Medical Information System	24	---	---
NIH/NCI 79-303	Analysis of Federally Sponsored Research in Low-Level Ionizing Radiation	73	---	---
NIH 80-301	Evaluation of the Consensus Development Process	---	---	---
NIH 80-302	Evaluation of Technology Transfer in Patient Management	160	---	---
NIH 80-304	IOM Study of Health-Related Effects of Marijuana Use and Abuse: A Research Agenda	114	---	---
NIH 80-305	Assessment of Research Doctorate Programs: Development of an Evaluative Tool	---	---	---
NIH 81-301	Evaluation of the Impact of RCDAs on the Recipients of These Awards	---	100	100

(cont.)

Proposed Budget (continued)

		Dollars in Thousands FY 81	FY 82	FY 83
NIH 81-302	Evaluation of the Impact of the Consensus Development Program	10	90	590
NIH 81-303	Analysis of NIH Data Bases in Support of Program Evaluation	2	23	---
NIH 81-305	Evaluation of Planning at the National Institute of Health	20	140	---
NIH 82-301	Effect of Stabilization of Research Grants on Academic and Nonacademic Biomedical Research Programs	---	30	200
NIH 82-302	Evaluation of Research Manpower and Training Evaluation Activities	---	75	75
NIH 82-303	A Method for Estimating MD Research Activity	---	18	---
NIH 99-999	Evaluation Program Support Costs and Computer Services	22	20	25
	Total FY 82 Set-Aside Request		$ 996	

NIH EVALUATION PROGRAM

FY 1982

INTRODUCTION

The Office of Program Planning and Evaluation (OPPE) in the Office of the Director, NIH, (OD/NIH), has central responsibility for NIH planning, evaluation, and legislative activities. The Program Evaluation Branch in the Division of Program Analysis has principal responsibility for both development and management of the NIH Evaluation Program. An important component of the NIH Evaluation Program strategy as described below is its continuing program of review and development of evaluation activities through the deliberations of two committee structures: namely, a standing Planning and Evaluation Officers' Committee and the Evaluation Oversight Committee, both of which are chaired by the Associate Director for Program Planning and Evaluation.

For both the planning and evaluation activities of the NIH Bureaus, Institutes, and Divisions, the Office of Program Planning and Evaluation in the Office of the Director provides guidance, professional assistance and review, coordination, and liaison within NIH and between NIH and other agencies and levels of government. In addition, evaluation studies of NIH-wide concern, including research support of cross-cutting areas, methods development, training and other support mechanisms, etc., are either guided or directed by OPPE and other OD staff. Beyond these functions, each BID has responsibility for carrying out its own program planning and evaluation activities.

Evaluation of Research

Underlying most NIH operations are two fundamental aspects of its organization and management structure: the essential autonomy (including separate appropriations) of the individual Bureaus, Institutes, and Research Divisions (BIDs) of the NIH and the peer review system of awarding grants and contracts in support of the pursuit of knowledge development and application in the biomedical sciences.

The peer review system of the NIH is the fundamentally evaluative structure on which the large majority of NIH operations and administrative procedures are based. The system is designed to assure that NIH will support the scientifically most meritorious and relevant biomedical research. To this end, it accesses the judgment of the most knowledgeable of the Nation's biomedical investigators. The system is based on two sequential levels of review, referred to as the "dual review system." The first level involves panels of experts, generally established along lines of scientific disciplines such as biochemistry, microbiology, immunology, etc. The panels, called Initial Review Groups (IRGs), are independent of the BIDs. They consist of 15 to 20 members and have, as their primary function, the review and evaluation for scientific merit of the research and training grant applications submitted to NIH for consideration of support. These groups are now reviewing in excess of 20,000 research and training grant

applications per year. Similar groups of peers are convened to conduct scientific reviews for Institute Center grant programs and to evaluate bidders on research contract solicitations.

The second level of review and evaluation is carried out by statutorily mandated National Advisory Councils or Boards that are appointed to each Bureau, Institute, or Research Division, and include representatives of public as well as research and academic interests. These groups have the responsibility to evaluate the appropriateness of the technical merit review recommendations made by the IRGs, to make a final judgment concerning scientific merit, and to make recommendations concerning program relevance. Advisory Councils and Boards also have the broader function of advising on the overall program of the BIDs. Subcommittees of Advisory Councils and Boards, supplemented as needed by selected specialists, often have a major role in the substantive deliberations that are a necessary component of the evaluation of nearly all NIH programs.

This dual review system is supported by extensive computer systems, which provide substantive classification information as well as detailed management and financial information about all applications, awards, and awardees. Through these systems, NIH programs can be monitored at any desired level of organization; the data elements on which to base NIH research support program accountability are routinely available.

Although NIH Bureaus, Institutes, and Research Divisions each have separate appropriations, NIH management functions are centralized, and the NIH Director provides leadership as well as liaison with higher levels of Government for all of the BIDs. An important mechanism through which the NIH Director participates in the planning and evaluation functions of the NIH BIDs is a program of semiannual reviews with the Directors of each of them.

The NIH evaluation program, through the availability of evaluation set-aside funds, provides a means of informing and improving the quality and the depth of the considerations that impinge on the deliberations of the several levels of decision-makers and advisors that participate in the development and management of NIH programs.

EVALUATION PROGRAM STRATEGY

In light of the dual review system described in the previous sections, the NIH program strategy goes beyond that dual review system to provide first and foremost basic intelligence needed by NIH executive and program staff in the management of NIH programs. It speaks to the need and emphasis on program and management information requirements.

Formal Evaluation Program activities provide opportunities to increase the quality and depth of program accountability. The standing Planning and Evaluation Officers' Committee, chaired by the NIH Associate Director for Program Planning and Evaluation, deals on a monthly basis with administrative and operational as well as substantive issues affecting the

spectrum of planning, evaluation, and legislation. The more narrowly focused problems of specifically developing and improving the program of evaluation activities at NIH have been addressed with the help of annually revised ad hoc committees. During FY 81, a central steering group, the Evaluation Oversight Committee, was established by the Associate Director for Program Planning and Evaluation; several subcommittees were also appointed to deal with specific problem areas. A notable feature of the current Evaluation Committee activity is the inclusion in its roster of representatives from both the Office of the Assistant Secretary for Planning and Evaluation and the OASH Division of Evaluation, Legislation, and Planning.

A significant focus of the efforts of both the Planning and Evaluation Officers' Committee and the Evaluation Oversight Committee during the past year has been the general question of how to improve the integration of program planning and evaluation activities. The Planning and Evaluation Officers' Committee has recommended revisions in the conduct of the Director's Review sessions (Attachment 1) and the Evaluation Oversight Committee has considered ways of improving the integration of evaluation into these and other planning activities. Two notable results of these efforts are:

- Adoption by OPPE of a plan to use Program Performance Summaries as the principal background document for discussion of defined program areas during the Director's Program Reviews (Attachment 2).

- Development of a modified and expanded guidance for the development of Program Performance Summaries (Attachment 3).

A second current thrust toward improvement of the NIH Evaluation Program is directed at the more general question of improving the utilization of evaluation project activities. All Institutes and OD offices have been requested to provide Impact Statements by July 1 for all evaluation projects completed since 1976. Review and evaluation of these statements will initiate the further consideration of questions and options concerning the dissemination and utilization of evaluation project results.

Prior to submission of Part II of the Evaluation Plan, the Associate Director for Program Planning and Evaluation will meet with each BID to review schedules for completing program performance evaluations and plans for using Program Performance Summaries in the Director's reviews. Following these reviews, a Technical Committee chaired by the Chief of the Program Evaluation Branch will conduct a technical review of all proposed evaluation projects.

EVALUATION PROGRAM

As noted above, evaluation projects that affect many or all NIH BIDs are planned and managed at the OD level. The Program Evaluation Branch provides administrative support, guidance, and consultative assistance for all OD projects, and initiates projects in the areas of methodology development,

support mechanisms, and manpower and training as needed. A suitable conceptual framework for describing OD evaluation project activities is the SATT paradigm (Science Base/Application/Technology Transfer/Training), which has been widely used in recent years to describe the distribution of NIH programmatic functions.

I. Science Base:

A. Ongoing Studies:

More than three-quarters of NIH programmatic activities are devoted to the support of research in the biosciences. As has been stated many times before, the fact that scientific research discoveries can neither be planned nor predicted argues strongly against the adoption of production-focused management paradigms and procedures in planning and evaluating NIH programs. Over the past several years, therefore, a major concern of the OD evaluation program has been the question of how NIH science base activities can best be evaluated. While it is apparent that the consolidated judgment of appropriate peer groups is the most widely accepted means of obtaining an integrated and comprehensive evaluation of NIH research support programs, it is equally evident that quantitative analysis and historical summaries of various aspects of program activities are needed to provide objective points of departure, or sometimes counterpoint, to the subjective judgments of such groups. The development and application of such methods has been one of the principal objectives of the OD Program Evaluation Branch. Quantitative methods have been developed for analyzing bioscience publications -- the principal first order outcome of NIH research grant support (NIH 73-2). Longitudinal records of training and research grant awards have been created to complement the annual cross-sectional records in the NIH IMPAC System (NIH 78-2). Now an attempt is being made to build bridges between the several information and management systems at NIH to improve access to them for use in program evaluation (NIH 81-303). Status of projects 73-2 and 81-303 is outlined below (78-2 was completed, and records are now being routinely maintained). One new project is planned in this area.

NIH 73-2 Evaluation of the Linkages Between Research Publication and NIH Funding

While the NIH IMPAC System has provided extensive information concerning the NIH investment in the production of research, quantitative evidence of the results of this support was not available prior to the establishment of the NIH Evaluation Program. The development of methods of analyzing scientific research publications or "bibliometrics," as it is termed, has been a major focus of the OD Evaluation Program. These studies have demonstrated the existence of meaningful maps and hierarchies in the structure of the bioscientific literature; they have shown that there are strong, demonstrable correlations between bibliometric indicators and the organization and funding of NIH bioscience research; and they have provided extensive evidence of the quality and validity of NIH research support programs.

During the current year, the focus of this effort is on completing the capture of publication and citation data through 1980 in the 275-journal set on which all NIH studies have been based, and on preparing program performance reports for all NIH BIDs (except NIA and NIEHS). The reports being prepared provide data on the 1970-76 publications supported by each BID in each of 52 scientific disciplines; they show relations between funding and publications and outline the role that each Institute plays in the development of biomedical disciplines, giving both quantitative and qualitative evidence of the results of BID research support programs.

The studies of NIH research performance have to date been limited to a 275-journal set because it has been necessary to obtain source-of-support information manually from the publications. January 1981 marked the beginning of a vastly broader potential scope for bibliometrics with the addition to NLM's MEDLINE of source-of-support information for all research papers. This new development greatly increases the utility of bibliometric methods for program performance evaluations, and also makes possible more fundamental analyses of the development of specialty areas within subfields of science. Making these capabilities accessible to BID program directors will be an important step toward effective utilization of these new tools. Some of the technical problems involved are being addressed in NIH 81-303 (see below); others may be the subject of future studies. No additional funds are required for this project.

NIH 81-303: Analysis of NIH Data Bases in Support of Program Evaluation

The purpose of this project is to develop the general capability to search existing NIH data bases for information on research and training awards, and research publications indexed by MEDLINE, and to relate these to program management data and information, so as to develop a strategy for computer-assisted short-term evaluations of NIH research programs.

Planning the computer search strategy is completed and test runs to provide the basis for feasibility assessments will be completed by the end of May. Full feasibility assessment will be completed by August.

Another type of OD evaluation effort in the Science Base area involves assessment of broad fields of biomedical research with which other agencies both within and outside of the Department of Health and Human Services are concerned. These projects arise generally because of Congressional or Departmental instruction or inquiry. Two such projects are currently underway.

NIH 79-303: Analysis of Federally Sponsored Research in Low-Level Radiation

Under the Biomedical Research Extension Act of 1978 (P.L. 95-622), the Congress directed the Secretary of HEW to: (1) establish a comprehensive program of research into the biological effects of

low-level ionizing radiation and (2) conduct a comprehensive review of Federal programs of research into the biological effects of ionizing radiation. The Director, NIH, was directed by the Secretary, HEW, in January 1979 to develop optimal strategy for Federally sponsored or conducted research into the biological effects of ionizing radiation. On the basis of the Secretarial mandate, in March 1979 the Committee on Federal Research Into the Biological Effects of Ionizing Radiation was created to undertake this and a number of important assignments. This Committee was succeeded by the Presidentially mandated Interagency Radiation Research Committee in April 1980.

For purposes of the evaluation of Federal research programs, a study with the National Academy of Sciences (NAS) was initiated under the aegis of the Committee on Federal Research Into the Biological Effects of Ionizing Radiation. This study, begun in July, 1979, was supported from NIH evaluation set-aside funds. Dr. Fredrickson, as Chairman of the Committee, created a subcommittee to oversee the Academy study. To facilitate the study, the Committee served as the focus for developing an inventory of all research into the biological effects of ionizing radiation conducted or funded by the Federal Government, with a brief description of the scientific objectives of each project. The National Academy of Sciences created a committee on Federal research on biological effects of ionizing radiation (FRIER) to oversee its effort. In September 1979, the Secretary, HEW, sent a letter to the chairmen of the Committee on Interstate and Foreign Commerce and the Committee on Science and Technology reporting on the work to date of the Committee and the NAS study.

Since June 1980, the study has continued under the aegis of the Presidentially mandated Interagency Radiation Research Committee. During this period, the Academy contacted principal investigators receiving Federal support for radiation research to obtain classification of their work, and a letter was published in Science to alert the investigators and the greater scientific community to the work of the NAS committee and its need for scientists' cooperation. In addition, the NAS sent request forms to grantees and contractors to obtain baseline information on their projects. Also, each agency provided, in summary form, processes for reviewing grants and contracts in this area so that the Academy, as part of its effort, could examine not only the research, but the administrative mechanisms for the review and funding for that research.

The study by the Academy has been completed and will be transmitted to Dr. Fredrickson as Chairman of the Interagency Radiation Research Committee on June 15. The report will be transmitted to Congress upon appropriate Committee review by June 30, 1981.

NIH 80-304: IOM Study of Health-Related Effects of Marijuana Use and Abuse: A Research Agenda

This project seeks to provide an independent assessment of the physiological and behavioral effects of marijuana use, and of Federal

research programs in this area. The IOM is reviewing the available scientific evidence that may suggest hazards to the health and safety of marijuana users; data on possible health benefits and medical utility are also being examined. Federal research programs will be carefully assessed and future directions delineated.

An IOM Steering Committee chaired by Arnold S. Relman, editor of the New England Journal of Medicine, is guiding the study, and several panels are examining various scientific aspects of marijuana use. On April 15 the parent Steering Committee heard the preliminary reports of these panels; a final report on the project is expected in December 1982.

NIH 81-305: Evaluation of Planning at the National Institutes of Health

Finally, as an appropriate correlate to efforts to improve the integration of planning and evaluation activities, NIH has undertaken an evaluation of the NIH Planning Process.

The first two phases of the ongoing evaluation project, NIH 81-305, have been titled "Feasibility Assessment of the Planning Process at NIH." The first phase will provide a descriptive analysis of the range of planning activities being conducted by the various Institutes. Planning activities are being analyzed and characterized in terms of similarities and differences among Institutes, and estimates of the dollar and manpower costs of each Institute's planning process are being made.

Based upon this descriptive analysis, in the second phase of the project a conceptual framework will be constructed from which several possible evaluative approaches can be considered. A number of models may be developed and the feasibility of these various approaches will be determined.

At this time, preliminary interviews have been conducted with Institute planning officers, and a preliminary listing of major planning process elements, documents, and resources to be examined has been developed. Considerations for determining the universe to be examined during the first phase of the study have been enumerated.

A working group has been organized, which will begin to meet in the near future. This group will construct the final design of the first phase of the evaluation study.

B. Proposed Study

NIH 82-301: The Effect of Stabilization of Research Grants on Academic and Non-Academic Biomedical Research Programs

During the past two years, in recognition that NIH budgets were not keeping up with inflation and were in fact likely to face direct cuts, NIH determined to place highest priority on maintainance of its

investigator-initiated research programs. A figure in the range of 5,000 grants has been set as the goal for "stabilization" of biomedical research, though this figure is subject to change pending appropriations. Most Institutes have anticipated that the stabilization policy would necessarily result in reductions in support of centers and training activities, and in use of the contract mechanism. Monitoring of actual changes in BID support patterns should be begun in the very near future, and plans made for subsequent analysis of changes in research output. If a suitable approach can be designed, it would be highly desirable also to investigate changes in academic and research center employment patterns. During FY 82, a task force will be formed to assist in planning details of this proposed study.

II. Medical Applications of Research and Technology Transfer

In this section are grouped evaluation projects that relate to the application of scientific knowledge to the practice of medicine. Two ongoing projects in this area are expected to be completed this year -- a study of the impact of clinical trials, and an assessment of technology transfer in patient management. In FY 82 a study of the effectiveness of the NIH Clinical Center's medical information centers will be completed. A study of the NIH consensus development process has been started, and a study of the impact of these processes is still in the planning stage. No additional projects are currently planned in this area.

NIH 78-5: Evaluation of the Impact of Clinical Trials on Medical Practice

This study has several objectives. The first is to evaluate the relationship between dissemination of the results of the Coronary Drug Project (CDP) and current clinical practice. The CDP was a trial of lipid-altering drugs in post-myocardial infarction patients. It was completed in August 1974, and final results were disseminated, beginning in January 1975. Traditional methods were employed in disseminating project results, including publication in recognized scientific journals, professional journals, scientific conferences, and news releases. Now that the information has had time to disperse through the medical practice system, it is opportune to find out whether these traditional techniques have been effective in translating CDP results into medical practice.

The study will also provide data on the use of aspirin in clinical practice for the treatment of post-myocardial infarction patients before and after results of the Aspirin Myocardial Infarction Study (AMIS) were published.

Lastly, the study aims to provide information about the rates and extent of adoption of two clinical treatments, and about current information transfer practices and, therefore, to improve post-trial dissemination techniques. The methodology developed during this

evaluation project will be useful in assessing the degree to which practicing physicians have learned about and adopted the results of clinical trials.

Practicing physicians from randomly selected large and small SMSAs* are being interviewed in a three-wave longitudinal design. Attitudes and beliefs about drugs studied in the Coronary Drug Project are being investigated, and an attempt is being made to obtain information about actual practices in prescribing drugs several years after the conclusion of the study; effects of a new dissemination of the study results (which occurred between interview waves) are also being investigated.

Over 900 physicians were interviewed after the CDP was completed, and before the AMIS results were released. The waves of post-AMIS interviews are currently taking place. These interviews will be completed in May 1981.

Variables included in the study are physican's age and specialty, geographic region, journal readership, etc. A final report will be available in September 1981.

NIH 79-302: Effectiveness of Computerized Medical Information System

The Clinical Center of the NIH has in place a computerized medical information system used to enter and track patient records, all medical orders, treatment protocols, and laboratory and ancillary orders and results. The purpose of this project is to provide information to enable Clinical Center management to make informed decisions concerning whether this system should be retained or replaced, and to provide the results of experience with the system to the hospital community. Specifically, the study must provide answers to these key questions:

- How well does the system work?
- How well has it facilitated medical care and the research missions of the Clinical Center?
- What are the relationships of the expenditures for the system to benefits from it?
- How well can the system meet the future care and research needs of the Clinical Center?

The study is being undertaken in two phases. In Phase I, methodologies and instruments were designed and tested so that the evaluation protocol could be appropriate to the Clinical Center environment. Phase II is the execution of the protocol and the application of the methodologies, culminating in a report of the findings and recommendations. This will be provided to the Clinical Center management and to the hospital community at large.

As of mid-April, detailed observations involved in work sampling, time study, and operational audit were well on their way to

*Standard metropolitan statistical areas.

completion in 23 distinct operational areas involving literally hundreds of areas of investigation. Technical performance measurements are ongoing and were virtually uninterrupted by the relocation of the main computer center on March 1. Over half of the more than 1,000 questionnaires have been sent to nurses, physicians, and other staff members. The cost-benefit analysis portion of the project, using adaptations of utility theory as applied to the Clinical Center's perception of the relative worth of systems ranging from no computerization through the maximum conceivable computer applications, will be conducted beginning in April. The preliminary findings and recommendations should be ready for presentation to the Project Advisory Group in September. Unquestionably the thoroughness of the project and its coverage, of both technical measurement and user perceptions of this integrated system, will provide much of the information the Clinical Center management needs to evaluate its future course of action with regard to hospitalwide medical information systems. The hospital community at large awaits the outcome of this study, since the potential expenditure for such systems is great and evidence of their value is not yet available.

NIH 80-302: Evaluation of Technology Transfer in Patient Management

A contract for this project was competitively awarded in 1978 to determine the influence of the medical/research center as a mechanism in facilitating the transfer of research results to community practice (technology transfer) and to develop methods for assessing the rate of adoption of medical technology in different types of institutions. Adoption of six selected technologies (listed below) is being studied in three types of institutions: NCI-supported cancer research and demonstration centers, community hospitals affiliated with the centers, and unaffiliated community hospitals -- all within 100 miles of each other. Plans are to study six such triads. The technologies that have been selected for study include mediastinoscopy; CT scanning; fiberoptic endoscopy, specifically colonoscopy and bronchoscopy; systems of disease staging; interstitial radiotherapy; and hormone receptor assays.

Through analysis of hospital records and interviews, data are being collected concerning rates of adoption of the six technologies during the 1970s, and factors associated with adoption.

Preliminary data analyses for six institutions (2 triads, each consisting of a cancer center, a community hospital affiliated with the center, and a community hospital not affiliated with the center) have been performed to date.

The preliminary data suggest that level and rate of adoption vary by institution type, depending on the technology under examination. For one of the technologies, centers showed the highest initial level of adoption but had the lowest rate of increase. Nonaffiliated institutions were the last to adopt the new technology, but their rate of increase exceeded the rate of increase shown by the centers.

In addition to the quantitative analyses described above, interviews are being conducted with hospital staffs to obtain judgmental information concerning factors associated with adoption.

Because of the complexity of this project, apparent in preliminary data, it has been decided that a new technical advisory group is needed to review plans for completion of the study. This review is scheduled for mid-May, and although it introduces a new delay, it should result in optimizing the productivity of the study.

NIH 80-301 and 81-302: NIH Consensus Development Program

NIH has recently assumed an expanded role in translating the output of biomedical research into knowledge, products, and techniques which can be effectively employed in the practice of medicine and public health, i.e., medical technology transfer. Specifically, within the last four years, NIH has initiated a consensus development program consisting of a series of activities to identify the extent of agreement and disagreement among relevant experts concerning various new and existing medical technologies and their role in health care -- whether they are scientifically sound, safe, effective, and suitable for introduction or continued use in practice. Consensus Development Conferences constitute the principal mechanism used by NIH to build consensus on these issues. Over thirty Consensus Conferences have been held, dealing with such issues as Cesarean childbirth, cervical cancer screening (Pap smears), and coronary artery bypass surgery.

The Office for Medical Applications of Research (OMAR) works closely with the various constituent Institutes to foster, aid, and coordinate efforts in the process of consensus development and disseminate the resulting statements, which contain the evaluation of the subject technologies and recommendations for their use. OMAR is responsible for the evaluation of effective procedures common to all Institutes, and has developed two evaluation studies of the consensus process and its impact.

NIH 80-301: Evaluation of the Consensus Development Process

The first part of this evaluation is aimed at answering the question of reproducibility: is the content of the Consensus Statement (the evaluation and recommendations for use of a medical technology reviewed in a consensus development conference) dependent only on the characteristics of the technology itself, or might the content of the statement generated vary significantly if the conference participants, setting, or guiding questions were changed? Phase I of the study (proposed time: 18 months), currently in operation for 6 months, involves a literature survey, collation of related studies, summarization of "state of the art" in group decision/consensus processes applicable to biomedical problems, documentation of group processes used in the consensus development program, delineation of operational (measurable) definitions of the goals and objectives for group decision-making in consensus programs, a classification scheme

for the consensus issues, identification of selection criteria for the panelists, and development of possible evaluation criteria. All of these activities, except the last, are underway. Phase II of the study will involve the design and execution of field experiments aimed at testing the effects (on the Consensus Statement) of varying the independent variables identified above, and any others identified as important in the course of the study.

The study is being conducted by the Center for the Research on the Utilization of Scientific Knowledge at the University of Michigan.

NIH 81-302: Evaluation of the Impact of the Consensus Development Program

This evaluation study is aimed at assessing the effectiveness of the means by which Consensus Statements are currently disseminated; the ways in which these might be supplemented or improved; and the effect that the statements and/or the information they contain may have on the knowledge and health-care-providing or health-care-seeking behavior of the recipients, particularly as this relates to the way in which the statement is written and disseminated. A Request for Contract is currently under review by a Project Technical Review Committee chaired by Dr. Carol Weiss of Harvard University. It is anticipated that the contract will have been advertised and proposals received for review by mid-July, thus allowing several-stage review and funding of the contract by the first quarter of FY 82.

III. Training

The Evaluation Oversight Committee has affirmed the need for an organizational commitment to research training evaluation and that it be vested in a person with the appropriate responsibility and authority to be appointed to the OPPE staff. That person would provide central leadership for current evaluation activities. A small select committee with appropriate representation from the Office of Program Planning and Evaluation, the Office of Extramural Research and Training, and the Division of Research Grants would be formed "to provide advice and consent." The report of the Committee was accepted by the Director, NIH, and permission given to seek an Expert or IPA appointment to meet the need. A search committee has further delineated the needs to be served into two general categories: (1) compilation of all available evaluation information about the operation and effectiveness of NIH training programs, and (2) development of long-term plans for further evaluation of training programs and of the effects of NIH training policies on biomedical research.

Currently, there is one Congressionally mandated evaluation ongoing in the training area, and one study that has been approved at the Departmental level but delayed, pending the availability of requisite staff. No new evaluations in this area will be undertaken until the anticipated review and planning process discloses specific unmet needs.

NIH 75-1: NAS Continuing Study of National Needs for Biomedical and Behavioral Research Personnel

This study has been conducted since 1975 under Congressional mandate by a committee convened by the National Research Council of the National Academy of Sciences. The current requirement extends through September of this year; the study's future is at present uncertain. In a series of annual reports the Committee has presented findings and recommendations responsive to these broad statutory aims:

- To establish the Nation's overall need for biomedical and behavioral research personnel, the subject areas, the kinds of training, and the number of individuals required to meet the need;
- To identify the kinds of research positions available; and
- To assess current programs conducted under the National Research Act in relation to other programs in order to determine if programs supported under this Act or modifications thereof are necessary to meet the national need.

A principal objective has been the development of a supply-demand model to project estimates of the need for health research personnel. The Committee has attempted this in terms of five broad areas:

- Basic biomedical sciences
- Behavioral science
- Clinical sciences
- Health services research
- Nursing research

In its conduct of the study the Committee has utilized consultants organized in panels dealing with these areas. The statutory provision for conduct of the study in consultation with the Director, NIH, is accomplished through presentation of progress reports at informal meetings of NAS and agency staff. The basic biomedical sciences and the clinical sciences have been subjected to the most intensive study, the former because of indications of possible overproduction, the latter because of the steep decline in the number of health professionals seeking research training.

NIH 81-301 An Evaluation of the Impact of RCDAs on the Recipients of These Awards

This study of NIH Research Career Development Awards has been delayed due to the unavailability of adequate staff in the OD Program Evaluation Branch. It is anticipated that an NIH-wide committee will oversee this project and play a major role in planning the design. While extensive committee participation can be expected to result in slower progress in the initial phase of the study, it will help to assure that the appropriate questions are investigated and that results will be used.

Attachment 1

Proposed Changes in the NIH Director's Review Sessions Excerpted From Report of the Planning and Evaluation Officers' Agenda Committee - August 12, 1980.

The Agenda Committee recommends that the two review sessions held each year between the Director, NIH, and the Institute Directors be retained, but that the purpose of these sessions be redefined and the meetings be restructured, as follows:

- Planning/Appropriation Briefing Sessions (December - January)

1. Purpose--The purpose of this session would be to brief the Director, NIH, for the Appropriation Hearings (FY 1982) and to provide the information and justification needed by the Director to subsequently establish tentative budget ceilings for the Institutes (FY 1983). The Appropriation Hearings are usually held in February, and other planning/budget documents (e.g., the NIH contribution to the PHS Three-Year Strategy Plan, which requires a 1983 NIH budget level) are usually due about the same time.

2. Timing--These review sessions would be held in December and January and would be scheduled from 45 minutes up to one and one-half hours.

3. Participants--The BIDs which receive an appropriation would participate: the research Institutes, DRR, FIC, and NLM. Briefing sessions would be held with the other service components (CC, DRS, DCRT, DRG, Office of Research Services) if mutually agreed upon by the Director, NIH, and the BID Director. The coordinating committees for the trans-NIH health problems would be asked to submit a brief statement of issues which might arise at the Appropriation Hearings. The Director, NIH, would then decide if a review session were necesssary.

4. Attendance--Both OD and BID attendance would be limited. OD participants would include the Director, NIH; the Deputy Director; Deputy Director for Science; Associate Director for Extramural Research and Training; Associate Director for Program Planning and Evaluation; the OD initial reviewer; OD planning, evaluation, and financial management staff; and others at the discretion of the Director. The BID Director would invite those senior support staff members he or she deemed appropriate.

5. Scope of Session--The following agenda would be covered:

   -- Present Fiscal Year (e.g., 1981): Several examples of areas of research holding great promise for progress and/or major advances and recent accomplishments.

-- Next Fiscal Year (e.g., 1982): Institute priorities and major program changes in the context of the FY 1982 budget process--the major focus of the session in preparation for the Appropriation Hearings.

-- Future Fiscal Year (e.g., 1983): Description and rationale for major program changes planned--directed to summary information and justification needed by the Director in subsequently establishing a tentative FY 1983 budget ceiling. The rationale for planned program changes should emphasize evaluation studies where appropriate.

-- Issues: Discussion of Institute needs for resources and personnel and any issues anticipated to arise at the Appropriation Hearings.

(In the case of those service components and trans-NIH coordinating committees for which a planning/appropriation briefing session were determined to be beneficial, the meeting would primarily focus on the issues identified that might arise at the Hearings.)

6. Documentation--Material submitted in advance of the sessions should be held to a minimum and be directly relevant to the agenda for the session, which will be patterned after the four major elements described under item 5 above. The Institute submissions, for which explicit guidance will be developed, can also form the core of the BID research plan submissions, which would then be modified after the sessions and included in the NIH Research Plan, to be prepared in early spring. Abbreviated summaries of the meeting highlights emphasizing followup actions would be prepared and shared with OD staff and other BIDs.

7. Rationale--Underlying this proposed change is the perception that a mutual briefing for the Appropriation Hearings is both necessary and desirable; however, inclusion of this objective within the context of the research plan review session has served to divert necessary attention from longer-range issues and concerns. This proposal retains the alignment of planning, evaluation, and budget processes and should provide a structure through which priorities and problems can be freely discussed.

- Program Review Sessions (Spring - Fall)

1. Purpose--These review sessions would provide the Director, NIH, and the Institute Directors with an opportunity to consider and explore program and policy issues of mutual interest, including major NIH policy changes and their implications (e.g., stabilization initiative), issues or problems facing a BID, long-range program developments and initiatives, reviews of research areas, and planning and evaluation activities. These sessions would not be tied to any specific budget event, would

combine both planning and evaluation concerns without being tied directly to the development of the research or evaluation plan, and would provide a forum for the discussion of science as well as management problems.

2. Timing--These review sessions would begin in the spring and extend through the fall, and would be scheduled for one to two hours. The sessions wuld be divided into two groups: the meetings with the research Institutes would be held from March through July; those with NLM, FIC, service organizations, and trans-NIH coordinating committees (as applicable) would be held from September through November.

3. Participants--All Institutes would participate, as well as DRR, DRS, DCRT, DRG, CC, NLM, FIC, and Office of Research Services. The trans-NIH coordinating committees would be asked whether a review session would be beneficial and, if so, requested to submit a brief statement of the issues to be raised. The Director, NIH, would then decide if a review session should be held.

4. Attendance--Attendance would not be limited and would include the Director, NIH, OD staff and supporting staff, Institute Director, and Institute program and supporting staff. Institute Advisory Council members and members of the Director's Advisory Committee would be invited to participate in these sessions.

5. Scope of Session--The scope of each session would depend upon the policy concerns that the Director, NIH, would like to explore that particular year and the items that the BID Directors wanted to raise. The agenda would be developed in advance by mutual agreement between OD and the Institute.

6. Documentation--Material submitted in advance should be limited and tailored to the agenda. A followup memo summarizing the discussion and the understandings reached would be prepared and widely circulated.

7. Rationale--This proposed change is intended to provide a context through which many of the needs identified by the BIDs could be met. It also would provide a forum for the Director, NIH, to share his proposals and explore their implications with the BIDs and representatives of the NIH constituency. The consolidation of the planning and evaluation sessions reflects the way in which these functions are structured in most of the BIDs. A primary consideration in recommending modifications to the central NIH processes has been to promote and support BID efforts to strengthen their individual planning and evaluation processes. Under this proposal, the evaluation plan can still be prepared in spring and early summer.

Attachment 2

Report of the Subcommittee (to the NIH Evaluation Oversight Committee) to Integrate Evaluation Activities into the Director's Review Sessions. January 27, 1981

A. Background

At its first meeting, the Evaluation Oversight Committee agreed to create a subcommittee charged to recommend ways in which the NIH and BID evaluation activities might be integrated with the Director's Review Session (DRS). The timing and purpose of the Director's Review Sessions were changed in the fall of 1980 based on recommendations from the so-called Moskowitz report. The report recommended that the Director's Review Session be divided into fall and winter sessions focusing on budget and appropriation issues and spring and summer sessions concentrating on program review.

B. The Potential Format of the Program-Oriented Director's Review Sessions

In order to develop its recommendations expeditiously, the subcommittee required some general idea of the format for the program-oriented sessions. The subcommittee assumed that the sessions would include: first, a general program review covering major highlights, problems, and plans across the science base, applications, and transfer and training and, second, a focus on a few (from one to three) program areas in some depth. The subcommittee feels that a focus on specific programs provides, perhaps, the best vehicle to couple program evaluation to the Director's Review Sessions.

C. Evaluation Requirements

In reviewing program evaluation activities, the committee noted that ASH/ASPE evaluation plan guidance stipulated that the Institutes are to submit a schedule for program performance evaluation covering their entire program. The schedule is to indicate dates for delineation of objectives, development and implementation of an information system to produce evaluation-related information, and completion of a summary of the program to date (a Program Performance Summary). In fact, NIH recently negotiated a guidance document for the program performance summaries. Thus ASH/ASPE requirements appeared to complement program review activity at NIH.

D. Strategy

The subcommittee elected to adopt the following strategy:

- To consider whether program performance summaries could serve as a background vehicle for program discussion during the Director's Review Sessions;

- To review the guidance document for its utility in the potential dual role of outlining the format for ASH/ASPE-required program performance summaries and background papers for program discussion during the Director's Review Sessions; and

- To offer suggestions on the types of evaluation-related information that would be useful to include in the program review.

E. Recommendations

1. The Use of the Program Performance Summary

The committee found that a modification of the program performance summary should be able to serve as a background document for the review sessions. In summary the changes include:

- An emphasis on the applicability of the summary to ongoing programs as well as concluded programs.

- The addition of a subsection on current and projected program activities as related to the program and management objectives.

- The inclusion of examples of the types of data and studies that may be employed in outlining program performance.

- A modification of the required statement on staffing.

The last point on staffing has been of concern to the subcommittee, who feel that too brief a statement on staffing may inaccurately portray the staff required to administer NIH programs. The subcommittee wishes to open the issue to the full committee as to whether and how to discuss staffing. The subcommittee also raised the question of whether and how intramural activities should be apportioned into programs.

2. Selection of Program Areas for Review

The sessions should be responsive to the needs of both the BID and NIH Directorates. Ideally, the discussion of program areas would coincide with the submission of program performance summaries to ASH/ASPE according to the Institute's agreed upon schedule in the Evaluation Plan. The BIDs may wish to focus on some areas more frequently, however, for reasons such as recent accomplishments, problems, political interest, pending legislation, and major changes in program activity emphasis or strategy. The subcommittee notes that the evaluation schedule should not dominate the schedule for program review in the Director's Review Sessions but, instead, provide a nominal schedule through which to cover, eventually, all program areas.

3. Reference to Evaluation Studies

The committee recommends that planned or completed evaluation studies be discussed in the program performance summary under Section III. The same section should note evidence of impact of study conclusions or recommendations from completed studies.

4. Lead Time

Since many, if not most, program areas to be reviewed are ongoing programs, sufficient lead time in setting the review meeting agenda should be provided. The subcommittee recommends that an agenda be set at least six weeks before the session.

F. Conclusion

The Program Review Sessions should be flexible to allow changes in format as necessary. The selection of only a few programs for discussion should deepen the OD staff knowledge of the scientific substance of the BID's programs as well as their knowledge of how the programs have been directed to achieve their accomplishments. The subcommittee feels strongly that much evaluation-related information already exists at NIH, and that much is now being developed through program evaluation activities. These studies can greatly assist the BIDs in management and in their communication with OD and the Department. Integrating this information into the Director's Review Sessions is a major step forward in this communication.

Members of the Subcommittee:

Dr. Helen Gee
Mrs. Elizabeth Hudson
Mrs. Gail Jacoby
Mrs. Joyce Johnson
Mr. Julian Morris
Dr. Kathleen Mullinix
Dr. C. James Scheirer
Dr. Edward J. Sondik, Chairman
Mr. Martin Strosberg

Attachment 3

GUIDANCE FOR PREPARING PROGRAM PERFORMANCE SUMMARIES

The purpose of program performance summaries is to summarize briefly what is known about program performance to date (efficiency, effectiveness, and responsiveness) in terms of a specific set of program objectives. These summaries will provide background information for Departmental/PCC decisions on budget increases or decreases, changes in legislation, and major changes in the administration of programs. These summaries are also to serve as a succinct program review document for use as background material for the NIH Director's Program Review Sessions. Program performance summaries should not exceed 10 pages. Format and content should be as follows:

I. Program(s) Description

A) The problems being addressed (quantified to the extent possible). This section should present a fairly nontechnical, but accurate, description of the program. It should describe the health problem the program attacks or, in the case of programs focused on a science area with no immediate health problem application (such as recombinant DNA research), the description should discuss the state of the science according to the major subprogram divisions. The section should summarize the size of the program and the health problems addressed, including statistics on morbidity and mortality, how these statistics may have changed over the past several years, and estimates of future changes in the statistics. The management-oriented structure of the program should be given in Section II.

B) A brief discussion of the legislative history of the program(s), focusing on legislative changes that have occurred since the program was established. Where programs are more than 10 years old, the section should briefly describe the initial legislation and outline the major legislative changes over the last 10 years. The discussion should include a succinct statement of the legislative origins of the program, and any background information related to Congressional intent.

c) Describe the funding and staffing of the program(s) for the years 1978-1982.

A history of the recent program funding levels would be particularly useful if the activities are categorized in terms of the different grant, contract, and training mechanisms employed and their dollar levels.

The following table format is recommended:

Grants	1978	1979	1980	1981	1982
R01					
P01					
Centers					
Other					
Contracts					
Training					
NRSA					
Others					

Staff directly related to the program should be enumerated and a statement included such as the following:

"It should be emphasized that the review of grants, site visits, program planning and evaluation, and other functions all require considerable staff. Noting total Institute staff at X persons, the prorated share of the total staff based on funding level is approximately Y."

II. Program Objectives and Activities

A) State the program and management objectives stated or implied in authorizing legislation and planning documents. Outline the terms in which achievement of these objectives can be assessed. Program and management objectives should be outlined according to the major subprograms. The objectives should be stated succinctly and to the extent possible in measurable terms.

B) Briefly Summarize the Current Program Activity

In order to give substance to the ongoing program, present a brief synopsis of the activities ongoing and projected to begin in the near term. Include grant and contract solicitations, clinical trials, demonstration, and other program activities. The discussion should relate the activities to the program objectives.

III. Evidence of Program Performance

This section should cite first, the types of information that are available and being used to monitor program performance, and second, evidence that assesses program efficiency, effectiveness, and responsiveness to mandate and to national needs. Evidence should be

included that is suggestive of program effectiveness, even where a cause-and-effect relationship cannot be firmly established. Program efficiency and effectiveness should be quantified where possible. Programs should be compared over time or against similar programs, as appropriate. Evidence of qualitative effectiveness should also be included, e.g., the establishment of quality controls or peer assessment of quality.

A) Outline the types of information that are being used by the agency or staff office to monitor program performance. Consider both quantitative and qualitative measures. Note specific data sources emphasizing evaluation activities. The data used to indicate program performance might include, for example, any measures associated with the peer review of grants (e.g., average priority scores,) and bibliometric analysis, as well as qualitative measures that may be provided by task forces and advisory committees.

Evidence of effectiveness should be presented in the following categories:

B) Evidence relating directly to stated objectives of the program.

C) Other evidence suggestive of program efficiency, effectiveness, and responsiveness. Some NIH programs have produced reports reviewing scientific areas (such as the product of state-of-science task forces) that may contain considerable evidence of progress, even though the primary purpose of the report was not to evaluate a program. Evidence and references should be cited in this section. In addition, a number of NIH programs categorize their grant and contract research according to the applicability of grants to specific programs and/or objectives. A summary of the numbers of grants and contracts and their funding may be a useful appendix in which to show progress in research effort.

D) Studies now under way that will assess program performance.

E) Proposed studies that will assess program performance.

IV. Major Issues or Problems Cited by Organizations Within the Administration, Congressional Committees and Organizations (GAO, CBO, CRS, OTA), and Interest Groups

State the major problems cited and describe actions taken to respond. The organization should be identified along with the problems it cites, e.g., "OTA stated in its report entitled _____ dated _____ that _____."

V. Other Major Barriers and Issues Relating to Program Performance

This should include any additional barriers which your organization sees as critical to improving program performance.

In discussing barriers, state what is now being done or proposed, including actions being taken by DHHS and other organizations involved and the roles each is playing. Examples might include the restatement of currently conflicting legislative requirements or the organizational location of certain program activities. Also include the discussion of issues which require resolution to make the programs more effective.

VI. Documentation

List the studies and reports used in preparing the program performance summary. The studies and reports should be numbered and should be referenced, e.g., "a recent study (7) found . . . ".

4

NATIONAL CANCER INSTITUTE

Dr. Vincent T. DeVita, Jr., Director

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Proposed Budget

		Dollars in Thousands FY 81	FY 82	FY 83
NCI/NHLBI 77-5	Evaluation of the Health Message Testing Service	66	--	--
NCI 78-3	Evaluation of the Effectiveness of Cancer Education	--	--	--
NCI 80-303	Evaluation of the Impact of the Estrogen Receptor (ER) Assay on the Treatment of Human Breast Cancer	--	--	--
NCI 80-304	Evaluation of the Comprehensive Cancer Centers Communication Network	--	85	65
NCI 81-301	Evaluation of the Information Program's Impact on Public Attitudes Toward Cancer	--	65	285
NCI 82-301	Evaluation of the Supermarket Information Distribution System	--	80 (5)	--
NCI 82-302	Evaluation of Activities of the International Cancer Research Data Bank (ICRDB) Program	--	35	15
NCI 82-303	Cancer Therapy Evaluation Program (CTEP) Information System	--	295	97.5 (97.5)
NCI 82-304	Evaluation of Community Oncology and Community Hospital Oncology Programs	--	300	--
NCI 82-305	Evaluation of the Cooperative Clinical Trials Outreach Program	--	125	--
	Total FY 82 Set-Aside Fund Request		$ 985	

Overview of NCI Evaluation Strategy

The goal of the National Cancer Institute (NCI) is to develop the means for reducing the incidence of and the morbidity and mortality from cancer. As the lead Federal agency in cancer, the NCI is responsible and accountable for the investment of public resources in the broad spectrum of research, control, and resource development activities required to achieve progress toward that goal. In doing this, the NCI views the process of evaluation as an integral part of all program and management operations. Evaluation is one of several dynamic, interactive processes that are blended to form a basis for making decisions to meet program needs. It is closely interrelated with budgetary operations and planning activities and is effective only if there is a continuous feedback of information among these activities. The NCI does not identify an organization unit for the purpose of conducting evaluation. Rather, evaluation is a continuous process performed throughout the Institute and at every level. The Office of Program Planning and Analysis is responsible for coordinating evaluation activities and for preparing an annual evaluation plan.

The rigor of the evaluation process and the approaches used for performance evaluation are dictated by the type of program or activity to be evaluated. For example, the results of training programs and construction programs can be evaluated upon completion. The results of a given research program may be evaluated regarding the degree to which program objectives are achieved, but an assessment of the impact of the research on the solution of a particular aspect of the cancer problem may not be possible for many years.

The National Cancer Act of 1971 (amended in 1974, 1977, and 1978), which created the National Cancer Program, contained specific provisions for review and evaluation processes. These provisions are still effective and valid. The following are a few examples of those provisions as stated in the Act:

> Sec.404. (a)(9) The Director of the National Cancer Institute shall, as soon as practicable after the end of each fiscal year, prepare in consultation with the National Cancer Advisory Board and submit to the Secretary . . . a report on the activities, progress, and accomplishments under the National Cancer Program during the preceding fiscal year . . .
>
> Sec.407. (a)(1)(c)(6) The Board may hold such hearings, take such testimony, and sit and act at such times and places as the Board deems advisable to investigate programs and activities of the National Cancer Program.
>
> The Board shall submit a report to the Secretary for simultaneous transmittal by the Secretary, not later than November 30 of each year, to the President and the Congress, on the progress during the preceding fiscal year of the National Cancer Program toward the accomplishment of its objectives.
>
> Sec.407. (a)(1)(B) . . . The scientists and physicians appointed to the Board shall be appointed from persons who are among the leading scientific or medical authorities outstanding in the study, diagnosis, or treatment of cancer or in fields related thereto, and at least two of the physicians appointed to the Board shall be physicians primarily involved in treating individuals who have cancer. Each appointed member of the Board shall be appointed from among persons who by virtue of their

training, experience, and background are exceptionally qualified to appraise the National Cancer Program.

(b) The Panel shall monitor the development and execution of the National Cancer Program and shall report directly to the President. Any delays or blockages in rapid execution of the program shall immediately be brought to the attention of the President. The Panel shall submit to the President periodic progress reports on the Program and annually an evaluation of the efficacy of the Program and suggestions for improvements, and shall submit such other reports as the President shall direct.

NCI evaluation activities deal with two major levels of operation: national and program. Aside from the Director and his staff, the individuals or groups responsible for the performance of these evaluations usually deal with only the program level. Internal studies to evaluate performance are frequently initiated by the Director and Division Directors in addition to those evaluation activities carried out by officially established external groups.

A listing of NCI evaluation activities, in the context of the two levels of operation, is presented in Table 1. As is apparent from the table, the NCI performs evaluation in a variety of ways other than through the one percent set-aside process. The majority of one percent set-aside evaluation projects are retrospective in character in that they are concerned with certain elements of programs that have been completed or program elements that are at a stage of development where an evaluation is appropriate.

At the national level, the concern is with the overall effectiveness of the total NCI effort and with NCI's role as the lead Federal agency in the National Cancer Program (NCP). National level evaluation activities are concerned with broad program strokes: program "balance:l relative investment of resources in the major areas of cancer research, control, and resource development; overall effectiveness of the National Cancer Program; coordinating the activities of the various National Cancer Program Components; etc.

The President's Cancer Panel, the National Cancer Advisory Board, and the Director, NCI, are primarily responsible for evaluation at this level. The President's Cancer Panel was established by the National Cancer Act of 1971 and is unique to the NCI. Its primary function is to oversee the efficiency and effectiveness of the operations in the National Cancer Program. In this role it has served as the sounding board for both the scientific community and the lay public, and as a result has had some impact on both the establishment of new program priorities and the modification of some established priorities. For example, the Panel played a significant role in increasing the emphasis on prevention research.

The major impact of the National Cancer Advisory Board (NCAB) stems from its responsibility for program review and evaluation in the larger context of the National Cancer Program. In this role, the NCAB advises the Director on major shifts in program emphasis, budget allocation, the desirability (or nondesirability) of initiating certain proposed programs, etc. The Board, through its several subcommittees, studies and analyzes every major aspect of program operations as a basis for providing the Director with its recommendations on program content and program priorities.

Table 1

NCI Evaluation Activities

Level of program operation	Type of activity	Performer	Frequency
A. National	1. Overall evaluation of NCI's total program effort including both science (quality, program "balance") and the efficiency of management and administrative procedures. Specific programs are reviewed in-depth by subcommittees of the National Cancer Advisory Board (NCAB) and the President's Cancer Panel. Special program reviews, which may include site visits, are also conducted. The Director, NCI, the NCAB, and the President's Cancer Panel prepare annual reports on the total program.	Director, NCI National Cancer Advisory Board President's Cancer Panel	Continually 4 times per year plus periodic special reviews for NCAB and President's Cancer Panel. Several internal studies may be ongoing at same time
B. Program	2. In-depth assessment of particular programs (e.g., immunology) for quality, need, relevance to cancer, reflection of current state of knowledge, appropriateness of level of support considering other program needs and priorities. Program presentations made by NCI program leaders and non-Federal scientists. Site visits may be included.	President's Cancer Panel National Cancer Advisory Board Boards of Scientific Counselors	4 times per year plus special review
	3. Evaluation of major NCI programs (e.g., clinical research) for accomplishments, new opportunities, current priority. Meetings are held periodically where NCI and non-Federal scientists evaluate program performance and make recommendations for following year.	All contractors and grantees for a specific program	Periodically
	4. Review of a completed program (usually non-research) selected by a Division for evaluation of accomplishments (e.g., effectiveness of Fellowship Training Program).	Contractors for 1% set-aside studies	Upon completion of study
	5. Evaluation of national research efforts in five organ sites which account for the majority of incidence and mortality from cancer. The NCAB Subcommittee on Organ Site Programs assures the NCAB that each program is well planned, adequately publicized, and properly managed, and that merit review of applications meets high standards. Subcommittee members are invited as observers to all meetings and workshops.	Organ site program working cadres (e.g., colon, prostate) and participating scientists. Breast Cancer Task Force NCI National Organ Site Programs Branch	2-4 times per year
	6. Evaluation of Cancer Centers Programs for content, quality of work, and contributions to the National Cancer Program. Site visits are made to each of the 21 comprehensive centers to evaluate them for "comprehensiveness." Profiles have been developed for centers as a basis for evaluation.	National Cancer Advisory Board	Periodically
	7. Staff groups appointed by the Director, NCI, to perform in-depth analysis and evaluation of NCI's research programs. These groups review all grant, contract, and intramural research in a given program area for adequacy of support, quality of research, priority relevant to needs of the national program. Their reports are reviewed by the NCI Executive Committee and submitted to the Director with recommendations for implementation.	NCI scientific staff and invited non-Federal scientists	Ongoing
	8. Development of NCI contribution to NIH Evaluation Plan including plans for both regular and 1% set-aside projects. Material is developed by program staff in accordance with NIH guidelines and is coordinated by the OD, NCI. Post-award monitoring and evaluation performed by respective program staffs.	NCI staff	Annually

The subcommittees on Planning and Budget, which in association with NCI staff prepare a 5-year program plan and associated budgets, and Environmental Carcinogenesis are examples of NCAB evaluation efforts at this national level.

Both the President's Cancer Panel and the NCAB prepare annual reports assessing the overall effectiveness of the NCI programs.

At the program level, evaluation is primarily directed toward the content, quality, and effectiveness of the major research, control, and resource development programs of the Institute from the perspective of divisional operations. The identification of new leads and opportunities, the establishment of specific priorities, and the determination of budget requirements and budget shifts are determined on the basis of results of evaluation activities.

The NCI has developed a system of classification and description of its activities referred to as the NCI Program Structure. Ten research programs, three control programs, and three resource development programs have been identified which span organizational units. It is in the context of this Program Structure that a Director's report and 5-year plan is prepared annually, describing National Cancer Program accomplishments, current activities, and program plans. Performance summaries will also be prepared for these programs.

The directors of NCI's five operating divisions are the major internal source of advice to the Director, NCI, on program content and program priorities. Each of the four divisions with program responsibility has a Board of Scientific Counselors, consisting of non-Federal scientists, which meets at least three times per year, in addition to site visits to the intramural programs, to review and evaluate divisional programs and provide advice and recommendations to the division directors on program content and priorities. These recommendations serve both as a major input to the division director in his decisions concerning the content, size, and direction of his programs, and in his recommendations to the Director, NCI, on the total effort of the Institute.

Examples of evaluation activities conducted by Boards of Scientific Counselors include an evaluation of the Cancer Control Program in the Division of Resources, Centers, and Community Activities, and an evaluation of the Clinical Trials Program in the Division of Cancer Treatment. The former resulted in a statement of the goals of the Cancer Control Program, which provides guidance for evaluation of the individual cancer control grants or contracts as well as evaluation guidelines for the entire Program. The latter 1) confirmed the need for a clinical trials sutdy section (now established), 2) resulted in the ongoing conversion of R10 grants and clinical research contracts to cooperative agreements, and 3) increased dissemination of cancer therapy information.

From time to time, special internal ad hoc working groups are formed to analyze and evaluate a specific program or activity. For example, a task force on occupational cancer was established to provide an overview of NCI's activities in occupational cancer and to make specific recommendations for NCI involvement in cancer epidemiology, experimental carcinogenesis, and cancer control and education. Also, an internal working group in the Research Facilities Branch, NCI, at the request of the National Cancer Advisory Board, evaluated future funding needs to improve clinical research facilities and standard research laboratory facilities at grantee institutions. The groups also evaluated the status of animal facilities at institutions conducting cancer research.

Program level evaluation is also conducted by the National Cancer Advisory Board. For example, the Board recently authorized an in-depth review and evaluation of the NIC Organ Site Program, a $15 million effort consisting of four grant-supported National Projects: the National Bladder Cancer Project, Large Bowel Cancer Project, Pancreatic Cancer Project, and Prostatic Cancer Project. The evaluation will be conducted by an outside (non-NCI) independent body. The group will evaluate each of the four projects with respect to planning and review activities, communication efforts (workshops, conferences, etc.), recruitment of new investigators, quality of science supported through the Program, and overall administration. The results of this evaluation will be reported to the Board and the Director, NCI, and will be used for decision-making regarding expansion or reduction of the Organ Site Program.

The majority of NCI set-aside evaluation projects are at the program level. These projects may evaluate an entire program, as identified in the NCI Program Structure or, as has been most frequent, a major component of that program. An example of the latter is a completed project (NCI 77-6) which was designed to:

> Phase I - Evaluate the Surveillance, Epidemiology, and End Results (SEER) Program, a major component of the Epidemiology Rsearch Program with an annual budget of $10 million.
>
> Phase II - Examine alternative methods and data sources for collecting cancer incidence and survival data other than by the present system of population-based tumor registries.

As a result of Phase I of this project, and intensive internal review, changes are being made in the organization, responsibilities, and scope of the program. Specifically, these changes include: 1) more participation in planning by potential users of SEER data, 2) expanded coverage of rural Southern populations with a substantial number of blacks, and 3) increased coordination with VA hospitals in gathering data. After careful NCI review of the alternatives suggested in Phase II of the study, it was determined that none would meet program goals better than the present network of selected population-based cancer reporting centers. The alternatives seemed to be oriented toward development of national cancer incidence estimates at the sacrifice of the goals of contrasting cancer incidence among population subgroups and of developing defensible data on cancer patient survival. Neither the Phase I nor the Phase II Report suggested that the present SEER Program design was faulty, only that there were aspects of program operation that could be improved.

The National Cancer Institute, as the agency responsible for the National Cancer Program, is required by law to provide the public with the latest information on cancer prevention, cause, early detection, screening, diagnosis, treatment, continuing care, and rehabilitation. The NCI has exercised this mandate through projects conceived throgh a process of needs identification and strategy development based on current message and audience data, and the delivery techniques available. Collectively these efforts constitute the NCI Communications Program. Several recently completed, ongoing, approved/not yet implemented and proposed NCI set-aside projects provide a focus for evaluating this $14 million communications effort. These include:

- NCI 77-2 Evaluation of the NCI Science Program Information System: A recently completed project which was designed to evaluate the NCI programmatic information systems in terms of their content, quality, capabilities, and usage. The goal of the evaluation project was to recommend ways of producing an integrated system that would provide accurate and timely comprehensive data fully meeting the needs of all users while reducing duplication of effort and excessive redundancy. The resulting study report highlighted a number of problems, including data overlap among systems, lack of comprehensive data in any single system, problems in information currency, and limitations in search capabilities and user documentation. Study recommendations included long- and short-range actions. Specific recommendations of this study are presently under review by NCI staff.

- NCI/NHLBI/OHIHP 75-5 Health Message Testing System: An ongoing study cosponsored by NHLBI, OHIHP, and NCI to determine methodologies for testing broadcast and printed health messages. The results of this testing will form the basis for recommendations/guidelines for message producers to use to develop effective broadcast messages and printed materials.

- NCI 80-304 Evaluation of the Cancer Centers Communications Network: An approved project, as yet to be implemented, to evaluate the Comprehensive Cancer Centers. Data resulting from this project will be used by NCI management personnel for decision-making regarding continued maintenance and support of the network. They will also be disseminated to each network office for use in increasing effectiveness and efficiency. (This project is also relevant to and impacts on the Cancer Centers Program.)

- NCI 81-301 Evaluation of the Information Program's Impact on Public Attitudes Toward Cancer: An approved project, as yet to be implemented, which will determine current levels of public knowledge, attitudes, and behaviors related to cancer. The study will be conducted in three phases:

  I - development work on study methodology and instrument design;

  II - pretesting of instruments, methodology, and analysis plan; and

  III - full-scale implementation.

  Phase I results are to be presented for review prior to initiating work on subsequent phases.

- NCI 81-303 Evaluation of Cancer Information Clearinghouse Products: An approved project, as yet to be implemented, to assess the utilization and value to users of 15 major, published bibliographies that have been widely circulated (500,000 copies) throughout the United States.

- NCI 82-301 Evaluation of the Supermarket Information Distribution System: A proposed project to evaluate the Supermarket Information Distribution System.

The NCI strategy for evaluating its Communications Program is to encourage the ongoing systematic review of specific communications activities and to use these reviews as tools which can form the basis for a future evaluation of the total NCI communications effort.

Regulations which affect the conduct of clinical cancer research have long been a concern to Clinical Cancer Research program investigators. A recently completed project (NCI 77-3) addressed the following: 1) whether the research subject is protected from undue risk and coercion by the current Federal regulations, 2) the unique satus of cancer patients as they relate to FDA and PHS guidelines concerning the risk:benefit ratio spectrum of toxicities of a new therapy, 3) the adequacy and compliance of obtaining informed consent from cancer patients, 4) the ability of Institutional Review Boards to competently analyze cancer treatment protocols, 5) the way in which the population of cancer patients, particularly those with advanced disease, perceive their involvement in treatment research, and 6) suggestions for modifying the existing regulations and procedures in order to improve cancer treatment research. Results and recommendations of this study are currently under review by NCI staff.

Diagnosis Program staff are sponsoring a project (NCI 80-303) to evaluate the impact of the estrogen receptor assay on the clinical management of patients with breast cancer. The NCI is interested in learning the extent that estrogen receptor (ER) assays are being performed on human breast cancer tissues, primary and metastatic, and the extent to which estrogen receptor assay results influence the clinical management of patients with breast cancer. In research settings the ER determinations have been shown to be useful in predicting response to endocrine therapy. There are also data that suggest that Stage II cancers of the breast that lack ER tend to recur earlier than those that are positive for ER, independent of the size of the tumor or the degree of nodal involvement. This study is designed to evaluate the application of these research gains in current clinical practice. The project is expected to be completed in June 1982.

The purpose of an ongoing study (NCI 78-3) in the Manpower Development Program is to develop a methodology for providing systematic evaluation of the effectiveness of Clinical Cancer Education grants. The study will provide information useful to medical and dental schools and their affiliated teaching hospitals. The means developed for program evaluation and monitoring will enable the National Cancer Institute to plan program developments, respond to inquiries, and prepare appropriate reports. The project is expected to be completed in September 1981.

New Projects Proposed

1. NCI 82-301 Evaluation of the Supermarket Information Distribution System: FY 82--$80,000

Supermarket display racks are used by at least eight Public Health Service agencies to distribute free publications to the public. For many of the agencies, including NCI, this distribution method is an integral part of the overall communications programs. The distribution system operates in 5,100 high-traffic supermarkets across 24 States, within the potential reach of 60 million shoppers weekly, with some areas designated as primarily black and Hispanic markets. The National Cancer Institute alone distributes approximately five million publications yearly through supermarkets. The total for the PHS is substantially greater.

This study would investigate the efficacy of the supermarket distribution technique, focusing on the distribution process.

The Office of Public Affairs, PHS, and the Division of Public Information, NIH, will cooperate with NCI in this evaluation effort. Their assistance would come largely in the areas of choosing market locations, helping prepare questionnaire items, determining which non-NCI publications would be used, reviewing findings, and disseminating the completed report to PHS agencies involved in public information. This evaluation will enable agencies to make decisions about their communications strategies and distribution methods based on careful research instead of on loosely perceived value.

2. NCI 82-302 Evaluation of Activities of the International Cancer Research Data Bank (ICRDB) Program: FY 82--$35,000, FY 83--$15,000

The ICRDB is an international information resource for cancer researchers throughout the world. It is an effective, multifaceted system for promoting the rapid exchange of cancer research findings among scientists for effective utilization. This project will evaluate the ICRDB data base system (called CANCERLINE) and a major series of technical publications (called Special Listings of Current Cancer Research Project Descriptions). Phases of the project will involve development of survey questionnaires; pretesting of the questions; revision, finalization, and OMB clearance of the questionnaire; selection and sampling of use groups; distribution of questionnaire; analysis of the results; and preparation and distribution of the final report.

3. NCI 82-303 Cancer Therapy Evaluation Program (CTEP) Information System: FY 82--$295,000, FY 83--$97,500, FY 84--($195,000)

The purpose of this project is to design and develop an information system and data base for the Cancer Therapy Evaluation Program. The system will provide scientific and administrative information on 1) treatment modalities (e.g., drugs, biological response modifiers, radiation and surgery), 2) diseases, 3) protocols, and 4) investigator teams. The project will require the development of a data base system that will consist of information on the objectives of proposed, active, and completed protocols and

provide data on the results of those protocols. In addition, it will provide for the establishment of a data base for treatment modality development and for disease treatment development. This system, when fully operational, should materially assist in evaluating the Clinical Treatment Research Program by providing access to the results achieved under various therapeutic regimens.

4. NCI 82-304 Evaluation of the Community Oncology and Community Hospital Oncology Programs: FY 82--$300,000

The NCI has initiated demonstrations of programs designed to improve the quality of cancer management in community hospitals. The Community Oncology Program (COP) is completed; the Community Hospital Oncology Program (CHOP) is in progress. This project is a full-scale evaluation of these programs.

An evaluability assessment has been proposed separately, to be carried out in conjunction with the Office of Evaluation and Technical Assessment (OETA). This project has been approved. The request for full evaluation is predicated on a successful outcome of the evaluability assessment.

Policy-makers need the evaluation information as a basis for future policy decisions. In addition, Congress has raised questions about the adequacy of NCI's attempts to transfer treatment technology to practicing oncologists. This evaluation will provide information relevant to part of that issue.

5. NCI 82-305 Evaluation of the Cooperative Clinical Trials Outreach Program: FY 81--$30,000, FY 82--$125,000.

The Division of Cancer Control and Rehabilitation (now DRCCA) initiated a program in which support was provided to cooperative clinical trials groups to facilitate their interactions with community oncologists, to increase the rate of cancer treatment technology transfer, and to upgrade the quality of cancer management in the community. The purpose of this project is to conduct an evaluability assessment, and to structure an evaluation is to determine whether the approaches used have been effective in achieving the goals of NCI, whether the output from these grants and contracts was worth the investment, and whether the results justify a continuation or expansion of this approach.

The populations to be assessed are five national and two regional clinical trials groups. Data to be gathered include objective measures of change in community oncology practices induced by the activities supported by NCI, indirect measures of change in terms of community oncologist exposure (increased numbers of seminars, tumor board meetings, etc.), changes in the numbers of patients from the community placed on protocol studies, changes in referral patterns of patients from the community to major centers, and other changes in the relationship between community oncologists and academic oncologists.

5

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Dr. Peter L. Frommer, Acting Director

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Proposed Budget

		Dollars in Thousands FY 81	FY 82	FY 83
NHLBI/NCI 77-5	Health Message Testing	66	--	--
NHLBI 78-5	Evaluation of Progress in Pediatric Pulmonary Diseases	2	167	--
NHLBI 78-6	Blood and Hypertension Research Manpower Data Base	5	--	--
NHLBI 78-7	Evaluation of the Impact of Adenine on Blood Banking	75	95	--
NHLBI 79-302	Evaluation of Health Hazard Appraisal in Work Setting Preventive Medicine Programs	--	--	--
NHLBI 79-304	Evaluation of the Effect of Sickle Cell Counseling	60	120	--
NHLBI 79-309	Evaluation of Hyperlipoproteinemia Dietary Manuals and Physicians Handbook	--	--	--
NHLBI 79-310	Evaluation of the Pulmonary Academic Award Program	--	--	--
NHLBI 79-311	Evaluation of Regimen Compliance	--	25	--
NHLBI 80-301	SCOR Mechanisms Evaluability	--	130	--
NHLBI 80-304	Evaluation of Statewide Hypertension Programs	38	124	--

(cont.)

Proposed Budget (continued)		Dollars in Thousands FY 81	FY 82	FY 83
NHLBI 80-306	Evaluation of Effect of High Blood Pressure Media Messages on Physicians	--	--	--
NHLBI 80-307	Evaluation of Nutrition Seminar Program	40	10	--
NHLBI 80-308	Evaluation of Sickle Cell Teacher Seminar	63	55	47
NHLBI 80-309	Evaluation of DBDR Erythropoietin Program	(41) --	--	--
NHLBI 80-310	Assessment of Audience Exposure to Television Public Service Messages on High Blood Pressure	--	102	54
NHLBI 80-311	Evaluation of Methodology to Aggregate Clinical Trial Results	--	--	--
NHBLI 81-303	Evaluation of Education Programs and Materials for Self-Management of Children with Asthma	--	55	28
NHLBI 81-304	Evaluation of Behavioral Medicine Program	23	27	--
NHLBI 81-306	Impact of Funding Decisions in the NHLBI Initiative Planning System	--	80	--
NHBLI 81-307	Evaluability Assessment of the Hypertension Detection and Follow-Up Program	37	83	--
NHLBI 81-310	Impact of Smoking Cessation Programs in the Federal Workplace	100	--	--

(cont.)

Proposed Budget (continued)		Dollars in Thousands FY 81	FY 82	FY 83
NHLBI 81-312	Evaluation of the SCOR Program	--	--	150
NHLBI 81-313	Evaluation of the Framingham and Other CHD Risk Models in a Large National Cohort	100	--	--
NHLBI 81-314	Evaluation of a Demonstration Program for Hypertension Control Using Community Health Centers	37	63	--
NHLBI 81-315	Feasibility Assessment of a Program to Measure Changes in Causes of Death	10	104	--
NHLBI 81-316	Evaluation of Postdoctoral Research Training	--	75	--
NHLBI 82-301	Evaluation of the Impact of NHLBI-CDC Lipid Standardization Programs	--	--*	--
NHLBI 82-302	Evaluation of the Impact of the Coronary Primary Prevention Trial and the Multiple Risk Factor Intervention Trial: Baseline Measurements	--	300	50
NHLBI 82-303	Interim Survey & Qualitative Research on Public Knowledge, Attitudes, and Behavior Regarding High Blood Pressure	--	50	--
NHLBI 82-304	Evaluation of Primary Reference Materials in Biomaterials Research	--	40	30
NHLBI 82-305	Impact of Nutrition Education Programs on Blood Lipids and Nutritional Status	--	100	50

(cont.)

*To be submitted separately

Proposed Budget (continued)		Dollars in Thousands FY 81	FY 82	FY 83
NHLBI 82-306	Evaluation of the Hypertension Detection and Followup Program (Phase II: Status of Health and Health Practice)	--	150	150
NHLBI 82-307	The Impact of Research Support Reductions on Large Grant Supported Programs	--	80	--
NHLBI 82-308	Evaluation of a Demonstration Program for Hypertension Control Using Community Health Centers (Phase II: Conduct of the Evaluation)	--	200	90
	Total FY 82 Set-Aside Fund Request		$2,205	

I. Overview of the NHLBI Evaluation Strategy

A. Policy Overview

1. Introduction

Evaluation is an integral component of the Institute management cycle: planning/implementation/evaluation. Evaluation provides the Institute Director and staff with the information necessary to determine the progress of Institute programs, the need for new programs, and whether existing programs are no longer required. The Institute views evaluation as the analytic partner of planning; responsible planning cannot take place without a strong analytic base, and it is the evaluation activity that provides this critical analysis of the Institute's program progress. As discussed below in more detail, the Institute is now embarking on an overall program review, first, to evaluate progress in the first 10 years of the National Heart, Blood Vessel, Lung & Blood Program, for which NHLBI is the lead agency; and, second, to revise its program plan in accordance with the results of the evaluation and a concomitant assessment of national health and research needs. The following sections of this overview outline the NHLBI program structure and the planning, implementation, and evaluation strategy, both necessary to understand the evaluation activities for Fiscal Year 1982.

2. NHLBI Program Structure

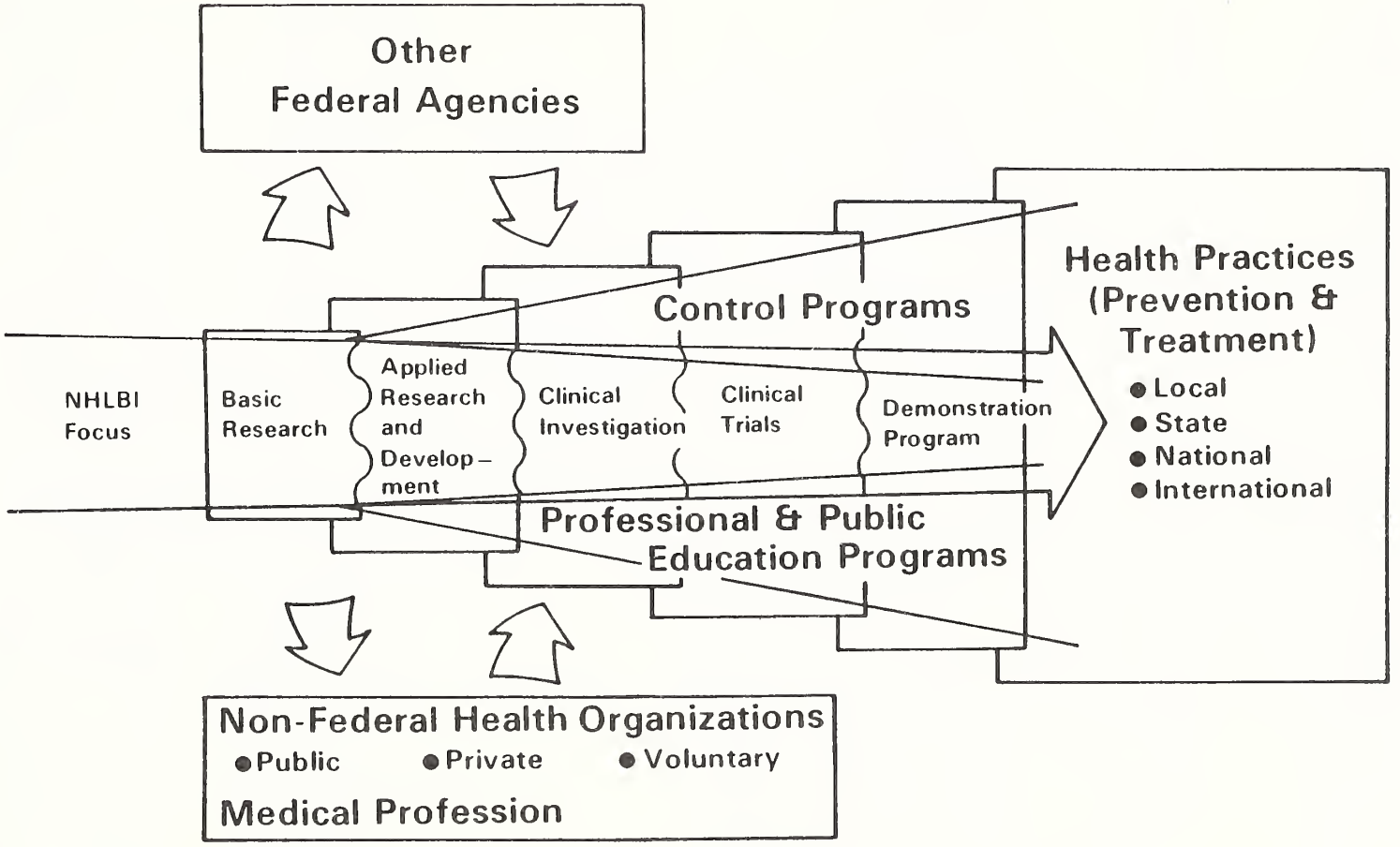
NHLBI research program activities encompass the full range of activities in the biomedical research spectrum: basic and clinical research, research application, prevention, education, control, and training. The National Program Plan, mandated under the National Heart, Blood Vessel, Lung, and Blood Diseases Act of 1972 and its subsequent reauthorizations, continues to develop knowledge concerning fundamental aspects of life processes, the etiology and pathogenesis of specific diseases, better approaches to preventing disease, and improved means of controlling diseases and their complications, and the timely and appropriate translation of this knowledge into improved health care and health care delivery practices that are effective, safe, and acceptable.

The NHLBI carries out its mission through a balanced National Program of knowledge acquisition, knowledge validation, and knowledge translation through demonstration programs, and professional and public education. The NHLBI program strategy is directed to maximize the beneficial impact on the public. The Institute Program continues to be based on the premise that prevention offers the greatest promise of reducing death and disability; prevention is therefore the primary goal of the National Program. Strong emphasis is also placed on controlling the painful and disabling complications of disease and on identifying those who are at high risk of developing diseases in the future.

Figure 1 provides a necessarily simplified depiction of this progression. However, in reality the process is complex, dynamic, and interactive. It has overlapping and interdependent phases, shows significant variation in the individual activities, and involves contributions from diverse organizations and groups throughout the country. Although Figure 1 portrays the underlying logic, each medical advance does not necessarily progress through each phase of the process

Figure 1

National Heart, Lung, and Blood Institute Continuum of Research



in the order shown. There are many possible entry and exit points, with evaluative information continually fed back to earlier phases of the research continuum. Much of the information gathering, analysis, and feedback take place under the NHLBI evaluation program. In the program descriptions to follow, the spectrum will be subdivided into three major areas for ease of discussion: Knowledge Acquisition activities, encompassing the spectrum from basic research through clinical investigation; Knowledge Validation activities, including primarily clinical trials; and Knowledge Translation and Dissemination activities, including demonstration and other programs related to the Institute's prevention, education, and control mandate.

3. Planning, Implementation, and Evaluation

For program management purposes, activity is subdivided into the following National Plan areas, developed as part of the National Heart, Lung, and Blood Diseases Program enacted in 1972.

Heart and Vascular Diseases

Arteriosclerosis
Hypertension
Cerebrovascular Diseases
Coronary Heart Disease
Peripheral Vascular Diseases
Arrhythmias
Heart Failure and Shock
Congenital and Rheumatic Heart Diseases
Cardiomyopathies and Infections of the Heart
Circulatory Assistance

Lung Diseases

Structure and Function of the Lung
Emphysema and Chronic Bronchitis
Pediatric Pulmonary Diseases
Fibrotic and Immunologic Lung Diseases
Respiratory Failure
Pulmonary Vascular Diseases

Blood Diseases and Resources

Bleeding and Clotting Disorders
Disorders of the Red Blood Cell
Sickle Cell Disease
Blood Resources

These three major subdivisions correspond to the Institute's three extramural program divisions and to the program areas identified for PHS reporting purposes. In addition to these 20 program areas, the Institute also has programs in training and research manpower development which are part of each extramural division's research program. Each of the 20 program areas may involve activities from basic studies to information dissemination.

The planning, implementation, and evaluation process is embodied in a yearly cycle which involves a continuous flow of information from the public, the medical community, other Federal agencies, and non-Federal organizations (Figure 2). This cycle is carried out primarily without evaluation 1-percent set-aside funds, which are used to augment the basic planning and evaluation cycle as needed. The Institute is responsible for coordinating this process and for developing required programs. The scientific community plays a prominent role

Figure 2

Steps in the NHLBI Planning Process

in both planning and evaluation through participation in various advisory and review groups, task forces, and working groups which assess program progress and determine future objectives and directions of the program. The scientific community participation is essential because of the inherent difficulties in assessing the relative values of research accomplishments and the relative values of alternative future program directions.

The process can be characterized as systematic, yet dynamic and varied in terms of specific approaches. It is designed to ensure a thorough review of the entire program as well as the implementation of new programs and the expansion, modification, or discontinuation of existing programs. This process involves five steps as follows:

- Review, assessment, evaluation, and initial planning of programs is done through a review of the goals, objectives, and progress of the Five Year National Program Plan with respect to the state of the science, as well as the impact of the program on medical care and the health of the public. This is accomplished with the participation of the NHLBI program staff, scientific advisory committees, and members of the general scientific community through workshops, task forces, and technical working groups convened to reach consensus on future directions for the program. The results of evaluation studies provide important input to this step. The products of this step are an update of the Five Year National Program Plan and a preliminary list of program initiatives and recommended program directions for future years, together with revised objectives where appropriate.

- Priority setting is the second step in the process, in which proposed new initiatives for implementation in the next year are ranked jointly by the staff of the Institute's categorical divisions and appropriate advisory committees.

- Implementation planning constitutes the third step, in which the staff of the categorical divisions and the Office of the Director convert the ranked initiatives into specific program plans including programmatic justification, management and fiscal plans, and funding mechanisms.

- Advisory Council review consists of a thorough review of the Implementation Plan by the full National Heart, Lung, and Blood Advisory Council. Council advice and recommendations are solicited and considered in developing the final NHLBI Implementation Plan and Program Budget.

- Program implementation consists of translating specific mandates and approved initiatives contained in the Implementation Plan into operational projects through various types of grants and contracts, intramural research, and collaboration with other Federal agencies through interagency agreements, as well as jointly supported international activities.

In addition, the NHLBI uses its management processes to plan for the expeditious and effective transfer of research advances as well as for scientific validation of new techniques for prevention and treatment.

4. NHLBI Evaluation Program:

4.1 Program Overview

NHLBI evaluation is carried out using a number of different mechanisms depending on the objective of the given evaluation effort. A significant portion of these efforts is carried out using set-aside program funds; the majority of the effort of evaluating a program of the size and structure of NHLBI is necessarily part of the NHLBI planning, implementation, evaluation cycle, supported through NHLBI operating funds.

The hierarchy of evaluation efforts can be represented schematically as shown in Table 1. Beginning at the most detailed level of the Institute program, the basic science research level, peer review serves as the primary mechanism to ensure that individual research grants are worthy of support. Research proposals are rated by the peer groups, the ratings reflecting research merit, need, and feasibility. Only those grants with the highest ratings are funded. The peer review system allows the funding of research to take place with a minimum of bias, ensuring that knowledge acquisition resources are targeted to research areas of highest merit.

The Institute's ongoing advisory groups perform several evaluation-related functions. First, they review annually program progress over all 20 program areas and across the three major categories of the research spectrum--basic science and training, application, and transfer. This assessment of progress and needs is translated with staff assistance and judgment into the National Heart, Blood Vessel, Lung, and Blood Five Year Program Plan. In addition, the groups review specific Institute research initiatives before they are placed in the Institute's annual implementation plan. Perhaps of most significance for the FY 82 Evaluation Plan, the advisory groups will be prominent in a major retrospective analysis of the first 10 years of the National Heart, Blood Vessel, Lung, and Blood Program. The result of the last such review forms the major portion of the Fifth Report of the Director, NHLBI, published in February 1978. Project 81-301 about to begin as of this writing will identify methods and data sources for the review, as well as methods for data analysis, for reviewing goals and objectives, and for setting of new goals and objectives.

The Institute has found that some program areas require an effort of such detail that a special working group must be convened with staff and consultant support. These working groups focus on areas of fundamental program importance or areas that cut across several program areas (such as prevention of cardiovascular diseases described below). Three of the most significant working group efforts have been the original (1971) Arteriosclerosis Task Force, the more recently completed Hypertension Task Force (1979), and the recently completed second Arteriosclerosis Task Force. The 1970 Arteriosclerosis Report influenced many of the program directions in the past decade and the extensive report of Hypertension Second Arteriosclerosis Task Force will very likely be as significant.

TABLE 1: SCHEMATIC OUTLINE OF NHLBI EVALUATION ACTIVITIES

EVALUATION ACTIVITY	PROGRAM ELEMENTS ADDRESSED	EVALUATIONS OBJECTIVES	FREQUENCY	FISCAL SUPPORT MECHANISM	PRODUCT
PEER REVIEW	BASIC RESEARCH GRANT APPLICATIONS	ASSESSMENTS OF INVESTIGATOR-INITIATED RESEARCH GRANTS	THREE TIMES PER YEAR	OPERATING FUNDS	RATING OF GRANTS
ADVISORY GROUPS	NHLBI DIVISION PROGRAM AREAS	ASSESS PROGRAM RESEARCH PROGRESS, IDENTIFY NEEDS, RECOMMEND PROGRAM ACTIONS	SEMIANNUALLY	OPERATING FUNDS	REPORTS TO DIVISIONS
ADVISORY GROUPS AND INSTITUTE STAFF	PROGRAM AREAS	UPDATE NAT'L PLANS: ASSESS PROGRESS TOWARD MEETING NAT'L PLAN GOALS: CORRELATE GOALS WITH NEEDS, REASSESS PROGRAM STRUCTURE	YEARLY	OPERATING	5-YEAR NAT'L HEART, BLOOD VESSEL, LUNG & BLOOD PROGRAM
WORKING GROUPS	PROGRAM AREAS OR CROSS-CUTTING PROGRAM ISSUES	REVIEW ACTIVITY, IDENTIFY NEEDS, FORMULATE AND RECOMMEND ALTERNATIVE PROGRAM ACTIONS	AS NEEDED	OPERATING FUNDS & SET-ASIDE FUNDS	REPORT TO INSTITUTE & TO RESEARCH CONSTITUENTS
FOCUSED EVALUATION PROJECTS	PROGRAMS AND PROGRAM COMPONENTS	FOCUSED ASSESSMENT OF PROGRESS: ESTABLISH GOALS & MILESTONES	AS NEEDED	SET-ASIDE FUNDS: OPERATING FUNDS AS REQUIRED	REPORTS TO NHLBI STAFF

The Institute employs targeted or focused evaluation efforts for those topics where more quantifiable and less subjective evaluation methods are appropriate. Such efforts are more easily applied to components of the program in the application or prevention, education, and control areas, and are the efforts most often supported through the set-aside funds. The general strategy for the NHLBI evaluation program is to seek an appropriate balance between the use of expert judgment to assess research progress and objective data to assess program impact.

4.2 Non Set-Aside Projects

The Institute's planning, implementation, and evaluation process is the mainstay of the Institute's management plan. Evaluation is stressed in this process through NHLBI Advisory Committees and the National Advisory Council. The primary overall program evaluation of the Institute's progress is made annually as part of the update of the National Heart, Blood Vessel, Lung, and Blood Program Plan. Each year, program objectives and progress toward meeting these objectives are reviewed by the Institute, and plans and objectives are identified for the following five years. This process makes extensive use of expert groups for the assessment of the basic research component of the plan, and calls, as needed, on expert judgment for evaluation of the other components. There is heavy staff involvement in this process, which the Institute has found to be responsive to its role of balancing Institute-originated initiatives with the need to support the diverse investigator-initiated research efforts required to move several fields simultaneously in the fight against heart, lung, and blood diseases.

The latest program plan will be published in June 1981 as part of the Eight Report of the Director, NHLBI. The development of the Ninth Report (and Plan) is now underway. The Plan, as reflected in a time schedule related to setting program objectives, performance indicators, a system for assessing program progress (described, in part, above) and program performance assessments, is included in an earlier section of this NIH Evaluation Plan.

The primary non-set-aside activity will be the major 10-year retrospective review of the National Heart, Blood Vessel, Lung, and Blood Program (as noted above). The activity will be preplanned, using set-aside funds as part of evaluation project NHLBI 81-301, and will be carried out under Institute funds as a component of the 10-year update of the National Plan.

Other evaluation-related efforts underway and not funded under set-aside funds include three working groups. Of major importance is the Working Group on Prevention and Education relating to Heart Disease. This group is establishing goals and assessing opportunities and needs for research regarding the prevention of cardiovascular disease and the education of health care professionals, patients, and the general public (both professional and lay) regarding cardiovascular disease.

Another effort is an examination of the Institute's progress, needs, and planning with respect to heart disease in childhood. This working group effort is emphasizing the study of the precursors of heart disease, their identification in children, and the potential for their early control.

Other ongoing activities include program reviews of the National Research and Development Centers as well as the periodic assessment of the Institute's Specialized Centers of Research.

4.3 Set-Aside Projects

Set-aside evaluation activities are generally directed toward both a National Program category and one or more areas of the Institute's biomedical research spectrum. In the following paragraphs, various evaluation-related activities are described in the context of, first, the research spectrum areas, and second, the National Plan areas they address.

KNOWLEDGE ACQUISITION AND TRAINING

Ongoing, Approved, and Recently Concluded Projects

Coronary Heart Disease

NHLBI 78-3 Evaluation of Prehospital Cardiovascular Care

This concluded project (NHLBI 78-3), co-funded with the Department of Transportation, has assessed the state of knowledge of the effectiveness of emergency care systems in dealing with prehospital cardiovascular care problems. The project compared existing studies on prehospital cardiovascular care, particularly as these studies reflect cardiovascular disease mortality. In addition, the project outlined requirements for future data collection. The report and conclusions from this project are due to be published in May 1981.

NHLBI 79-306 Workshop on the Decline in Coronary Heart Disease

Project NHLBI 79-306 sought full and won partial support of an NHLBI workshop to evaluate the possible causal factors involved in the decline of coronary heart disease. Evaluating the reasons behind the decline will enable the Institute to plan its programs to continue or accelerate the reduction in mortality. The workshop provides the basis for a detailed Institute evaluation of the reasons behind the decline and its relation to NHLBI programs. The workshop took place during early FY 1979 under Institute auspices. Its recommendations have led to new Institute efforts to exchange information with other agencies on causes of death, to retest the applicability of the Framingham risk model (NHLBI 81-313) and explore other research initiatives on causes of death and changes in arteriosclerosis.

NHLBI 79-307 Conference on Coronary Prone Behavior

This project sponsored a working conference (December 1978) on coronary prone behavior (CPB). The results of this conference are now being disseminated and include: (1) a clearly delineated position on each aspect of the CPB problem in terms of the value of the research done to date, (2) the legitimacy and validity of the conclusions based upon this research, (3) a critical and objective review of the statistical procedures and design employed in the studies, (4) an intensive analysis of the theoretical underpinnings of the CPB concepts from physiologic, cardiologic, psychologic, sociologic, anthropologic,and epidemiologic standpoints, (5) whether intervention studies are yet justifiable on the basis of existing research findings, and (6) a synthesis of this data combined with recommendations for future activities in this area.

Lung Diseases

NHLBI 79-310 Evaluation of the Pulmonary Academic Award Program

The Pulmonary Academic Award Program, an innovative approach to increasing pulmonary manpower, seeks to improve the education of physicians and conseqently, the delivery of health care. This award program is designed to improve the basic pulmonary curriculum in a medical school through curricula change and faculty educational development. This project is to conduct a study aimed at (1) assessing

the overall impact of the Pulmonary Academic Award program, and (2) identifying those program characteristics and approaches that contribute to the "success" of an individual program. A contractor has been chosen and the study is underway.

Pediatric Pulmonary Diseases

NHLBI 78-5 Evaluation of Progress in Pediatric Pulmonary Diseases

The Division of Lung Diseases is currently involved in the detailed planning of this approved evaluation project,which will assess the progress made in the National Heart, Lung, and Blood Institute Pediatric Pulmonary Diseases Program since 1972. The Institute Program in Pediatric Pulmonary Diseases seeks to prevent, if possible, and improve the prognosis for patients with cystic fibrosis, bronchiolitis, and respiratory distress syndrome (RDS). The main questions to be addressed under this project are: (1) What progress has been made in pediatric pulmonary disease in meeting the goals outlined at the inception of the National Plan? (2) What directions or goals seem appropriate for future development? During the project, a steering committee will make extensive use of the judgmental assessments of scientists from the areas of interest. Progress in the research areas will be assessed by experts formed into small working groups. Each working group will examine a particular area of pediatric pulmonary disease research. The working groups,in concert with the steering committee and other consultants as required, will use the results of this analysis to formulate directions for future development.

Training

NHLBI 78-6 Blood and Hypertension Research Manpower Data Base

This project is developing a data base to enable the Institute to (1) estimate and track the pool of researchers now included in blood and hypertension research, (2) assist in the assessment of past training programs and (3) develop future projections for research training. The project has periodically queried investigators involved in the research areas as to their activities and interests. A final report is now being prepared and the information system is being turned over to the Institute.

Evaluation Methodology

NHLBI 78-4 Evaluation of Progress in Hypertension and Pulmonary Research

This completed project tested the use of bibliographic and citation analysis in determining whether research progress can be measured quantitatively using these techniques in a narrowly-defined research area. The project has shown that these techniques can provide critical, quantitative data on research progress, and enable the Institute to better relate its actions to eventual program outcomes. Such measures would be important adjuncts to the advisory committees and working groups currently employed by the Institute as a primary measure of research area change. The Institute expects these methods to be used on the update of the National Program Plan.

Research Mechanisms

NHLBI 80-301 Assessment of the SCOR Mechanism

This project will address the important question of the effectiveness of the Specialized Centers of Research (SCOR) program mechanism. This mechanism, now under extensive use by NHLBI, was designed to provide an interdisciplinary research milieu to address research problems of national significance within the NHLBI purview. Institute experience may now be sufficient to allow the productivity of these centers to be compared with the more traditional alternative research mechanism of individual investigator-initiated grants. This project will determine the feasibility of, plan for, and conduct a pilot assessment of the effectiveness of the SCOR mechanism and in so doing will be of significant importance to the Institute's future programming and its response to research needs. A competition under small business set-aside was unsuccessful; a new solicitation is underway.

Blood Diseases

NHLBI 80-309 Evaluation of DBDR Erythropoietin Program

The objective of this completed project was to evaluate the Division's erythropoietin program with regard to procurement of raw material, purification of the hormone, and distribution to the scientific community. The procurement and distribution program began in 1960 at the recommendation of the Hematology Study Section. It was expanded in 1976 at the recommendation of the DBDR Advisory Committee, when an RFP for procurement and and RFA for development of purification methods were issued. The final report for this project is in preparation. It is now appropriate that the existing system be reevaluated in light of current and future needs in order for the Institute to determine its strategy for continuation of the program.

National Program

NHLBI 81-301 Evaluability Assessment of the National Heart, Blood Vessel, Lung, and Blood Program

Since the inception of the National Program in 1972, NHLBI has led the program under a highly structured framework of goals and objectives. This project is proposed to develop the approach and (if necessary) the methodology to be applied to the evaluation of a decade of research and the identification of objectives and outcome measures for the future program. Because the National Program is wide-ranging, covering the full spectrum of research from knowledge acquisition to its transfer to the health practitioner, the project will review several research sub-programs to determine available data and methodologies appropriate to the task. It is expected that several alternative methodologies will be required, depending on the characteristics of the research area and the extent of NHLBI past involvement in the area.

Evaluation Methodology

NHLBI 81-315 Feasibility Assessment of a Program To Measure Changes in Causes of Death

Mortality rates by cause and demographic status are major indicators of progress against disease, and the NHLBI uses and depends heavily on such measures in the evaluation of its programs. A longitudinal cohort study of cause of death among a random sample on 4.7 million persons has been proposed to be performed by the National Center for Health Statistics and the Census Bureau. The methodology, based on the newly developed National Death Index and on the latest Census data, will estimate annual probabilities of death by cause and numerous demographic characteristics. This project will evaluate the feasibility of the methodology. The results from the project will be critical in deciding whether to proceed with the larger study, modify it, or develop methods to correct for bias. The project is now underway.

National Program Planning

NHLBI 81-306 Impact of Funding Decisions in the NHLBI Initiative Planning System

As part of the NHLBI planning process, representatives of the community and staff and Divisional Advisory Committee members suggest program initiatives for possible implementation the next fiscal year. Each initiative is discussed and rated by both Advisory Committee members and Institute staff. After collective judgment of the importance of the topic, timeliness, feasibility of approach, and need for work in the field, all initiatives are given priority ratings. Because of funding limitations many of the high priority initiatives are not implemented in the following year or in subsequent years. The impact of funded initiatives is available from progress reports and the Institute management system; however, the impact of not funding initiatives is not clear. This project will examine selected initiatives that have not been funded because of funding limitations for fiscal year 1972-73. A state-of-the-art review will be held for the 1972-73 time period for each area. An evaluation study will then examine the progress of scientific accomplishments and the change of the state of art through fiscal year 1980.

Research Mechanism

NHLBI 81-312 Evaluation of the SCOR Program

The SCOR program now represents an Institute investment of over 10% of the extramural budget. These centers hold the promise of innovative, effective research approaches to problems of significant national need in this unique blend of thematic research with clinical, basic, and interdisciplinary research approaches. Evaluation project NHLBI 80-301, Evaluability Assessment of the SCOR Mechanism, is now under implementation, and scheduled to conclude in

September 1982. If so recommended and approved by NHLBI, this project will implement the evaluation plan developed and tested under NHLBI 80-301.

Training

NHLBI 81-308 Evaluability Assessment of the Minority Hypertension Research Summer Program

This project will address the feasibility of, and plan for evaluating, the Minority Hypertension Research Summer Program. This program encourages minority biomedical students and faculty toward biomedical research careers through a focus on hypertension research. The program is now in its fourth year and has progressed to the point that an evaluability assessment is appropriate. Activities under the project will include: the identification of the objectives of the Institute, the minority institutions, and the research centers included in the program; and identification of measures for evaluating progress toward these objectives. Of particular importance will be the evaluation planning to relate short-term objectives reflective of program performance to the long-term objectives related to research careers. An RFP is under preparation.

NHLBI 81-316 Evaluation of Postdoctoral Research Training

An important aspect of the Institute's National Program is the support of research training and manpower development. Of particular interest is postdoctoral training, because it is at this juncture in the career of a scientist that a commitment to a given research field is made. This project will develop and test methodologies for evaluating the impact of NHLBI-supported postdoctoral training. The project will investigate the extent to which NHLBI-supported researchers were trained by NHLBI/NIH, and the relative success of former NHLBI-supported trainees. Depending on the results, a full-scale evaluation may be indicated. This project is now underway using in-house resources.

KNOWLEDGE ACQUISITION AND TRAINING

New Projects Proposed for FY 82

NHLBI 82-304 Evaluation of Primary Reference Materials in Biomaterials Research

One of the purposes of NIH programs is to enable effective research to be undertaken, whether directly or indirectly supported by NIH. One of NHLBI's programs in the devices and technology area seeks to characterize physicochemical and biological properties of biomaterials, particularly materials that may be used in cardiovascular disease-related devices. In 1979, NHLBI awarded contracts for the preparation and distribution of three such materials. The purpose of this project is to assess the impact of these materials on experimental procedures and the communication of results. The project would first identify current laboratory and reporting practices and subsequently characterize the use of these materials in biomaterials research. The results of the project would be used to consider whether the program should be continued.

NHLBI 82-307 The Impact of Research Support Reductions on Large Grant Supported Programs

The recent decline in National Institute of Health funds has resulted in the withdrawal or threat of withdrawal of support from a number of large research programs. Some of these programs have been active for more than a decade, developing and transmitting new knowledge, applying it to patient care, and providing a training environment for health scientists. It is important for NHLBI and NIH to understand the effect of changes in funding on these institutions. This project will assess institutional response to funding change as well as the response of individual scientists to their choice of research directions. The project is important to the Institute and NIH as they continue to improve its understanding of its funding policies.

KNOWLEDGE VALIDATION - CLINICAL TRIALS

Ongoing or Approved Projects

NIH 78-5 Evaluation of the Impact of Two Clinical Trials

This important NHLBI project, underway and funded under the OD Evaluation set-aside as part of the 1978 Evaluation Plan, is developing and testing a methodology to evaluate the impact of clinical trials on medical practice. Two trials will be addressed, including the Coronary Drug Project and the Aspirin Myocardial Infarction Study.

NHLBI 79-311 Evaluation of Regimen Compliance

This project, submitted as part of the 1979 plan, is evaluating the compliance measures used in assessing the progress of clinical trials. Compliance is a key to effective clinical trials, and it is of critical importance in many of the NHLBI clinical trials which rely on patients to administer their own therapies such as not smoking, eating particular foods to lose weight, etc.

NHLBI 80-311 Evaluation of Methodology To Aggregate Clinical Trial Results

In order for a clinical trial to be undertaken, a balance must be met between the uncertainty of the effects of the regimens under test, the potential impact of the clinical trial on health practice and on research, and the scientific information available to buttress the trial. To assess the state of information concerning a therapy's efficacy, it usually is necessary to aggregate the information from several small clinical trials. This project proposes to test a methodology for evaluating the results of previous trials by combining these results patient-by-patient using multivariate techniques. Several small clinical trials on low-dose heparin, a promising therapy for preventing pulmonary embolism and deep vein thrombosis stemming from major surgery, will serve as a test for the methodology. A final report on the project was recently submitted and is in review.

All these projects are part of an ongoing Institute effort to maintain already high standards and improve where necessary the Institute's activities in this critical aspect of the research spectrum.

Evaluation Methodology

NHLBI 81-313 Evaluation Methodology Development: Prediction of Health Status

It is of critical importance to the design and evaluation of health programs that we be able to predict health status and identify reasons behind discrepancies between prediction and realized outcome. The major tools used to predict health status with respect to life and death and various cardiovascular events is the Framingham risk model, derived from the 20-year Framingham study. This project will validate and update the Framingham model, based on the current health status of the 15,000 adults in the original cohort of the Health and

Nutrition Examination Survey conducted in 1971-74. The project will be performed in cooperation with the National Center for Health Statistics as well as the National Institute on Aging. The project represents a unique opportunity to refine an evaluation and research tool of inestimatable value to biomedical research, and, moreover, to our future health status.

Hypertension

NHLBI 81-307 Evaluation of the Hypertension Detection and Follow-Up Program

The Hypertension Detection and Follow-up Program (HDFP), one of the Institute's large scale clinical trials, concluded in January 1980. This $70 million program has shown the effectiveness of treating relatively mild hypertension. This project will continue and expand the Institute's efforts to track the impact of this trial. The project will focus on Institute and other efforts to disseminate results of the trial, on changes in health practice, and changes in public knowledge. A conference will be held in June to assess and discuss the implications of this trial for patients, physicians, and the public at large.

KNOWLEDGE VALIDATION - CLINICAL TRIALS

New Projects Proposed for FY 82

NLHBI 82-302 Evaluation of the Coronary Primary Prevention Trial and The Multiple Risk Factor Intervention Trial

These large-scale clinical trials are scheduled to terminate in 1983 and 1982, respectively. The Coronary Primary Prevention Trial is determining whether cholesterol reduction by drug therapy will significantly lower coronary heart disease rate in a group of hypercholesterolemic but otherwise healthy men; the Multiple Risk Factor Intervention Trial (MRFIT) is assessing whether a special intervention program to simultaneously lower serum cholesterol, reduce blood pressure, and eliminate cigarette smoking will result in a significant reduction in mortality from coronary heart disease. In essence the CPPT is testing the so-called lipid hypothesis; MRFIT is testing the effectiveness of lowering several risk factors simultaneously. This evaluation project will assist the Institute in two ways: first, it will help the Institute determine whether and in which ways the clinical trials have affected practice, and second, it will assist the Institute in disseminating the results of the trial for maximum effectiveness. The project will survey current physician practice toward treating patients with elevated risk factors, the survey to take place before the results of the clinical trials are released. Subsequently, another survey will be performed after the results of the clinical trial have been released to determine clinical practice. The results from the first survey will be used by the Institute in designing the dissemination program for the clinical trials.

NHLBI 82-306 Evaluation of the Hypertension Detection and Followup Program (Phase II: Physician Practice)

This project will continue evaluation project NHLBI 81-307, Evaluation of the Hypertension Detection and Followup Program. The latter project is a broad-based effort to determine the impact of the trial. The project proposed here will focus on the change in physician practice related to hypertension detection and treatment. A previous study was performed under joint FDA/NHLBI sponsorship in 1978. The Hypertension and Detection and Followup Program (HDFP) has recently extended validated therapy for high blood pressure to the mild and moderate blood pressure ranges. There is a growing feeling, however, that the stepped-care approach to therapy, which attempts to use non-pharmacologic means to control blood pressure before drugs are used, may not be widely adopted. The survey to be conducted under this project and the previous survey will provide important data to the National High Blood Pressure Education Program and to the investigators of the HDFP on current practice and will therefore provide information on appropriate directions for information dissemination. (Because of the need to make this survey and the previous survey compatible, it is not anticipated that this project will be a direct component of NHLBI 82-302, above; however, it is expected that the projects will be coordinated.)

KNOWLEDGE TRANSLATION AND DISSEMINATION

Ongoing or Approved Projects

Hypertension

Several projects underway relate to the Institute's transfer activities in high blood pressure education.

NHLBI 77-3 Evaluation of Patient Tracking Systems

This completed project assessed experience to date on hypertension treatment compliance (patient tracking) systems. The results of an inventory of systems, which identified and characterized systems nationwide, has shown that no system has been demonstrated to be effective but that several seem to have potential. The results from the study identified the need for Institute involvement in this area and led to the development of a guide for such activities.

NHLBI 78-1 Survey on Hypertension Awareness, Knowledge,and Behavior

This activity completed in April 1980, is a six-year follow-up survey on public knowledge and behavior with respect to high blood pressure (NHLBI 78-1). This survey provides a major benchmark for the Institute in its efforts to determine the effectiveness and needs with respect to high blood pressure education. The report is now being printed and has already proven useful to the Institute in its high blood pressure programming.

NHLBI 80-305 Evaluation of Compliance Improvement Program

A weak link in the chain of hypertensive control is the failure of patients to follow through on the health provider's recommendations for treatment. Recognizing this problem, the Institute sponsored a grant program to develop a better understanding of, and improve methods for,achieving compliance. The purpose of this project is to evaluate the results of the grants supported under the program, to integrate these findings with other recent work on compliance, and to formulate recommendations on future research for the Institute. In addition, the project is developing recommendations for the National High Blood Pressure Education Program on actions to improve patient compliance.

Media-Related Projects

NHLBI 77-5 Health Message Testing

Co-sponsored by the National Cancer Institute and the Office of the Secretary, HHS, this project is developing a system for pretesting health education messages before these messages are made final and distributed to the media. The first stage of this project (NHLBI/NCI 77-5) developed and tested TV messages. This project continues the testing of the system and expands it to include print testing as well as the electronic media. The project is in its final year.

NHLBI 80-306 Evaluation of the Effect of High Blood Pressure Media Messages on Physicians

This project will assess the impact on physicians of popular media messages aimed primarily at patients. Health education and promotion programs reach both patients and physicians, yet their effect on physicians is not known. This project will address whether health professionals are influenced or reinforced by information in the general mass media, including public service announcements on radio or TV, and messages in local newspapers. A contractor has been engaged and the project is underway.

NHLBI 80-310 Assessment of Audience Exposure to Television Public Service Messages on High Blood Pressure

Perhaps the major NHLBI effort directly related to prevention, education, and control is the National High Blood Pressure Education Program. This program utilizes a variety of mechanisms to increase public and professional awareness of the dangers of hypertension and ways of treating the problem. The electronic media are used extensively in the program. In order to determine the effectiveness of the media on a nationwide basis, it is necessary for the program to know the extent to which these messages are aired. This project will monitor on a periodic basis the airing of messages across the country. The NHBPEP program has a high investment in such messages, which must be used to be effective. If the messages are not being used, or are used during non-prime time, the program will be able to respond, for example, by changes in message style, or by direct discussions with program managers. Procurement difficulties have postponed implementation of the project, but resolution is expected by April 30.

Hypertension and Other Risk Factors

NHLBI 79-302 Evaluation of Health Hazard Appraisal in Work Setting Preventive Medicine Programs

As part of its research program, NHLBI is determining ways to effectively implement risk factor reductions. Part of this effort is concerned with programs at the workplace. This project seeks to evaluate the potential of health hazard appraisal to serve as a vehicle for establishing and conducting effective hypertension and other risk factor control programs at the workplace and to establish data collection procedures and analysis to be used to evaluate the workplace efforts in health hazard appraisal. This project is currently underway and making satisfactory progress.

NHLBI 80-304 Evaluation of Statewide Hypertension Programs

This project will perform an interim evaluation and develop a final evaluation plan for the 5-year NHLBI efforts in statewide control of hypertension. Several contracts with State agencies in Connecticut, California, Georgia, Maine, Maryland, Michigan, and South Carolina are designed to encourage and coordinate efforts to combat high blood pressure. The project is underway, and a draft evaluation plan has been prepared.

Arteriosclerosis

NHLBI 79-309 Evaluation of Hyperlipoproteinemia Dietary Manuals

As part of its information dissemination activity, the Institute disseminates therapeutic diet manuals to physicians for their patients. This approved project is intended to evaluate the impact of the five hyperlipoproteinemia therapeutic diet manuals and accompanying handbook for physicians in terms of: physician and patient use of the information, whether and to what extent the materials should be revised and/or augmented, and the distribution mechanism. In addition, the project will enable the Institute to better understand whether the dissemination mechanism has potential in other treatment areas. The project is now awaiting OMB survey clearance.

NHLBI 80-307 Evaluation of the Nutrition Seminar Project

This project related to prevention, education, and control will evaluate an Institute effort to improve and maintain the training and knowledge of hyperlipidemia practicing nutritionists. An experimental series of regional workshops will be evaluated to determine how effective the workshops are and whether they can be effectively conducted on a nationwide basis without Institute assistance. The workshops are primarily directed at those elements of diet and nutrition related mainly to reducing cardiovascular risk. A contractor is now carrying out the project.

Blood Diseases

NHLBI 79-303 Evaluation of Prevention, Education, and Control Activities in the Field of Blood

This project will begin in late FY 1981 and coincide with the beginning of the National Program update. Its goal is to evaluate the progress of blood-related prevention, education, and control activities undertaken in the Division of Blood Diseases and Resources, NHLBI. The 1972 mandate from Congress (P.L. 92-423) calls for coherent prevention, education, and control programs as part of the NHLBI implementation of the National Heart, Blood Vessel, Lung, and Blood Diseases Program. This project will evaluate the program to date, assess current and future needs, and formulate alternative future actions.

Sickle Cell Disease

NHLBI 77-4 Evaluation of Sickle Cell Education

The National Sickle Cell Disease Program was initiated in 1972 as a major collaboration effort to accelerate research in and to improve diagnosis, education, and treatment of sickle cell anemia. The National Heart, Lung, and Blood Institute within the National Institutes of Health (NIH) was named as the lead agency with responsibility for the coordination of the National Program. The purpose of the current project (NHLBI 77-4) is to evaluate a major component of the National Program, the Sickle Cell Education Program. The Education Program was created to increase public awareness and understanding about sickle cell anemia. Toward removing the misconceptions and improving public awareness of the problem, the program has sponsored continuing education programs by centers and clinics and provided factual information through films, lectures, workshops, seminars, tutorial conferences, and printed material. The program is aimed at three target

populations: those populations at risk; the medical community, and the general public. This project is evaluating the program's progress and strategies thus far, emphasizing the effectiveness of the program for each of the target populations; the project will also outline areas for future emphasis and develop baseline data on the target populations' awareness and behavior toward sickle cell disease.

NHLBI 79-304 Evaluation of Sickle Cell Counseling

This project, funded under the set-aside program, is being rescheduled to begin late in Fiscal Year 1981. A conference held in July 1980 provided information and recommendations essential to the project. This project will evaluate the effects of sickle cell counseling programs conducted as part of the National Sickle Cell Disease Program. The focus of this project will be much narrower compared to the education evaluation project aimed at several target populations. The new project is aimed directly at evaluating the psychosocial effects of counseling related to the counselors' feelings, attitudes, and behavior. The contractor has been selected and the project is set to begin.

NHLBI 80-308 Evaluation of Sickle Cell Teaching Seminar

An innovative NHLBI program in high school teacher education is underway to convey to science and biology teachers information on Sickle Cell Disease. These teachers in turn, will pass this information on to their students, who are the target audience for much of the NHLBI Sickle Cell Disease program. This effort in communicating the facts about this disease, and in dispelling the myths about it, will be evaluated through this project. A contractor is now being selected.

Blood Resources

NHLBI 78-7 Evaluation of the Impact of Adenine on Blood Banking

The goal of this ongoing project is to assess the impact of an increased shelf life for blood. As a result of extensive research over the past 15 years, it has been found that the addition of adenine to blood cells for transfusion will permit the extension of the storage period from 21 to 35 days. Limited studies with computer models have suggested that this extension of the outdating period will result in more efficient use of blood, especially by hospitals with a low volume of transfusion. The overall project goal is to obtain a measure of the efficiency with which red blood cells are provided for medical use before and after adenine becomes available. In effect the project has two goals-- one related to impact of a line of research and the second related to a change in the blood resources system.

Hypertension

NHLBI 81-314 Evaluation of a Demonstration Program for Hypertension Control Using Community Health Centers

One of several steps in the dissemination of the results of the recently completed NHLBI clinical trial, the Hypertension Detection and Follow-up Program (HDFP), is a demonstration of a hypertension control program in a community health center setting. This evaluation project is the first phase of a three-

phase project to evaluate the demonstration program. The project will involve the design of a format for the conduct of the demonstration, the design of an evaluation methodology, the selection of sites, and the collection of necessary baseline data. The implementation and evaluation of the demonstration will be performed in subsequent phases over a five-year period. The results of the evaluation are expected to identify how much of the clinical trial protocol can be implemented in an existing health care system, and whether the approach is economically feasible. The design phase is now underway using a panel of consultants and in-house staff.

Pediatric Pulmonary Diseases

NHLBI 81-303 Evaluation of the Pediatric Asthma Self-Management Program

There is increasing recognition of the importance of self-management in cases of pediatric asthma. A number of Federal and non-Federal agencies have mounted programs to encourage and to improve the effectiveness of pediatric efforts to date, analyze the need and health system resources required for such self-management, and outline future objectives and related progress measures for the several programs. We expect the project to be carried out in the following stages: (1) identification of self-management efforts in pediatric asthma as well as self-management efforts of a similar nature, such as those related to juvenile diabetes; (2) modeling of the pediatric asthma patient and his environment to identify needs and resources required for self-management; (3) evaluation of the guidance and educational material available; (4) assessment of the costs of self-management; and (5) identification of future objectives and outcome measures. This project is jointly sponsored by NHLBI and NIAID and will involve other Institutes at NIH as well as the Health Services Administration. The project is in the planning stages and will be implemented, based on the results of a non set-aside sponsored conference to be held in June 1981.

Smoking

NHLBI 81-310 Impact of Smoking Policies on Smoking Activities in the Federal Workplace

Smoking is a major risk factor for heart disease and cancer and is a major cause of illness in our society. The anti-smoking campaign launched by HEW and private organizations has been vigorous. This project will examine the impact of Federal policies on both the anti-smoking activities and the level of smoking in the Federal workplace. The project is important not only for the assessment of the Federal policies but as a model to measure the impact of such policies in the private sector. The project will be implemented under the auspices of the NHLBI Interagency Technical Committee Working Group on Smoking and Heart, Lung, and Blood Disorders. This working group represents fourteen Federal agencies and assists in the implementation of the National Heart, Blood Vessel, Lung, and Blood Program. NASA, OPM, and NIDA have expressed keen interest in this project and their representatives will serve as the project's executive committee. The project is now under contractor solicitation.

KNOWLEDGE TRANSLATION AND DISSEMINATION

New Projects Proposed for FY 82

NLHBI 82-301 Evaluation of the Impact of NHLBI-CDC Lipid Standardization Programs

Lipids are one of the primary risk factors related to cardiovascular disease. Elevated cholesterol levels may indicate an increased risk of cardiovascular disease,while increased levels of high density liproprotein may indicate a reduced risk. One of the aims of the NHLBI-CDC Lipid Standardization Programs has been to encourage more precise and accurate lipid measurements in community and cardiovascular research laboratories. This project will evaluate the effect of this program. The evaluation is intended to meet the information needs of the NHLBI and CDC program managers. The evaluation will also inform the cardiovascular research and clinical laboratory communities of the accuracy and precision currently extant and emphasize the need for further improvements, if necessary, for clinical and epidemological purposes.

NHLBI 82-303 Public Knowledge, Attitudes, and Behavior Regarding High Blood Pressure: An Interim Assessment

This project is designed to gather ongoing national trend data on public knowledge, attitudes, and behavior for a limited number of areas in the National High Blood Pressure Education Program. In addition to a random sample of individuals across the United States the survey will also include focused group interviews with hypertensives and family members to provide additional detail. The project will be implemented as additional questions to a routine survey conducted by one of the national polling organizations.

NHLBI 82-305 Impact of Nutrition Education Programs on Blood Lipids and Nutritional Status

One of the integral parts of the Multiple Risk Factor Intervention Trial (MRFIT) is a nutrition education program. This program is essential to the behavior change that is essential to the hypothesis under test in the trial. This project will use biochemical measurements of adherence to compare and validate the various measurements of long-term dietary adherence now at use within the MRFIT. Moreover, using methodology identical to that in use in the NCHS Health and Nutrition Examination Survey (HANES), the project will assess the nutritional status of the sample of MRFIT participants. Because dietary modification techniques are an integral part of the coronary risk factors reduction program,it is essential to determine the nutritional status of persons who place themselves, or are placed,under dietary regimens designed to increase coronary risk protection. In addition, this project is essential to the formulation of future public policy regarding American dietary patterns and their goals for the 1980s.

NHLBI 82-308 Evaluation of a Demonstration Program for Hypertension Control Using Community Health Centers (Phase II: Conduct of the Evaluation)

Phase I of this project (submitted as NHLBI 81-314) is now developing an evaluation strategy to assess the impact and effectiveness of the application of methods used in the Hypertension Detection and Followup Program in community health care centers serving minority populations. The development of the evaluation methodology is currently underway, as is the selection of sites and a determination of the necessary baseline data. Beginning in FY 82,the evaluation itself will be undertaken. Changes in the funding of these community health care centers (now anticipated to be funded through block grants) may necessitate a change in evaluation strategy. In any case this project will carry out evaluation as specified by the working group convened under the current project.

4.4 Emphasis for FY 82

The Institute will continue to assess the overall program progress in implementing the National Heart, Blood Vessel, Lung, and Blood Program. As described earlier in the plan, the Institute's research programs are constantly under analysis through the planning and evaluation process, as well as through working groups and advisory committees and the set-aside program. Over the coming year, progress toward goals in all the planning areas will be assessed and reported in the Annual Director's Report. As progress toward goals is made, the Institute's program plan is appropriately modified. In general, the evaluation program emphasis is broad, which reflects this management plan. However, one area will be preeminent over the coming year--the overall evaluation of the programs, as part of the 10-year update of the National Heart, Blood Vessel, Lung and Blood Program. Other activities include emphasis on the review of prevention, education, and control activities, particularly those related to hypertension and sickle cell disease; the assessment of progress since the establishment in 1972 of the National Program; and a continuing emphasis on clinical trial evaluation activities.

4.5 Summary

In summary, evaluation activities are carried out under Institute operating funds and from the 1% set-aside funds. The set-aside funds are, of course, limited to evaluation-related activities. Specific projects that are deemed appropriate for the set-aside funds are selected and incorporated into the Institute's Evaluation Plan, which is submitted to NIH and, after review, becomes part of the NIH Evaluation Plan. Set-aside projects represent the primary mode of the Institute's evaluation activities which in total are an integral part of the Institute's management plan activities.

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Evaluation of Clinical Trial Coordinating Center Model Project

Definition and Description of Program

Large-scale clinical trials may cost over $100 million and require some 7 to 10 years to complete. The major organizational component of a large-scale trial is the coordinating center, which collects and analyzes patient data, monitors and coordinates the intervention, monitors trial safety, and serves as a communications center between the program staff and the intervention sites. A typical coordinating center may consume from 10 to 15 percent of the trial's fiscal resources. To assess and improve the operation of these centers, the Institute launched a study of coordinating center solicitation and operation.

Evaluation Study Performed

Design of Study

The objectives of the project were to identify coordinating center policy, objectives, roles, responsibilities, and authority; to establish coordinating center cost and other management data; and to assist in the reduction of duplication of effort as new coordinating centers are developed. The project design focused in detail on ten multicenter clinical trial coordinating centers, seven of which represented National Heart, Lung, and Blood Institute trials and three represented trials of other Institutes. Information concerning the management and operation of the different studies and their coordinating centers was obtained in several ways, including standardized self-administered questionnaires and meetings with project office staff, coordinating center staff, and clinical center personnel. In addition, coordinating center and clinical trial documents were reviewed extensively, including manuals of operation, the clinical trial data collection and reporting forms, procedures manuals, and publications. The contractor for the study was the University of Maryland.

Findings and Recommendations

There are deficiencies in the solicitation of the coordinating centers, with Requests for Proposals providing insufficient detail on the proposed trial's background, organizational structure, design, specific duties, and expected computational demands.

Effective coordinating center operation is a complex management task, because most centers are located in a university setting, with a diversity of activity. Principal recommendations included:

- Periodic systematic review of the overall trial performance;
- A proposed organizational structure for the coordinating center within the university structure;
- A center management organization structure based on functional groups with delineated responsibility and authority;
- Early recognition of personnel problems by management, and preparation to deal with them effectively.

The field of clinical trials is relatively new and lacks identity. Consequently, trial design and operation are not part of a specific management or scientific discipline, which leads to difficulties in establishing standards for trial operation and to poor exchange of information.

Implementation Results

- The National Heart, Lung, and Blood Institute has modified its solicitations for coordinating centers to include many of the study recommendations and makes available to the applicants information from the existing clinical trials;
- A review of the extensive data on clinical trial operation and organizational structure is under consideration to improve overall trial effectiveness and efficiency;
- A clinical trials professional society has been formed and a journal has begun publication to improve methodology and information sharing on the management and operation of clinical trials and coordinating centers;
- National Heart, Lung, and Blood Institute clinical trial project managers encourage the clinical trial investigators to employ appropriate management techniques and make periodic comprehensive site visits to coordinating centers and to intervention sites.

References

Reports by the Clinical Trial Coordinating Center Model Project, available from NHLBI, Bethesda, MD 20205:

I. Study Design and Methods

II. RFPs for Coordinating Centers: A Content Evaluation

IV. Terminology

VI. Phases of a Multicenter Clinical Trial

XIV. Enhancement of Methodological Research in the Field of Clinical Trials

XVI. CCMP Manuscripts Presented at the Annual Symposia on Coordinating Clinical Trials

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Evaluation of Patient Tracking Systems

Definition and Description of Program

In 1972, the National Heart, Lung, and Blood Institute undertook the conduct of the National High Blood Pressure Education Program to measure public and professional awareness of the danger of hypertension, to encourage patients to seek treatment, and to encourage physicians and other health professionals to maintain patients on appropriate treatment. Patient compliance to treatment is a critical factor in hypertension control, and identified professional knowledge of individual patient compliance is as critical to successful control. This study reviewed existing systems to "track" or follow patients under treatment, assessed the actual or potential success of the systems, and formulated a model tracking system.

Evaluation Study Performed

Design of Study

The first stage in the project, performed by the NHLBI National High Blood Pressure Education Program (NHBPEP), was to identify exemplary hypertension control programs that included patient tracking. These programs were identified by several sources, both within NHBPEP and through provider organizations such as pharmacies, hospitals, etc. Some 2,000 contacts were made, with over 300 responses received. From these responses, a large volume of data was collected and some site visits were made. These data allowed NHBPEP to formulate and categorize the various patient tracking approaches currently available. In addition, NHBPEP has been able to outline the evaluative needs of these patient tracking systems.

Results of Data Analyses

- Some 300 hypertension control programs have tracking components, although most are rudimentary.
- Few data are available on the costs or benefits of patient tracking. Estimates of cost vary from a few dollars for some systems to over $50 per patient per year for other tracking systems.
- There is little, if any, communication among tracking system users about system development and experience.

- In some systems, medical charts are used for recordkeeping; others use ad hoc records that vary greatly in the type and amount of information recorded.

- Compliance rates reported by programs seem to be related to the mode of contact, increasing with personal contact.

- Although many programs keep adequate records, they lack staff to analyze and interpret data.

- Overall, programs with patient tracking systems report higher control rates than programs with no tracking component.

Implementation

The National High Blood Pressure Education Program has taken the following actions based on the results of the study:

- An extensive guide to developing and operating patient tracking systems has been prepared and is scheduled for wide distribution to hypertension programs.

- Patient tracking is now emphasized as an important component of a hypertension treatment program by the program staff in their consultation with State and local control programs. The recent Hypertension Detection and Followup Program (a 7-year clinical trial) findings have greatly enhanced interest in tracking because of the widespread knowledge that tracking and followup played a major role in the notably successful outcome of that trial.

- The program is acting as a repository and analysis center for data information and data on patient tracking activities.

References

A Guide to Patient Tracking Systems, National High Blood Pressure Education Program, NHLBI, 1980.

Final Report: Patient Tracking Systems, National High Blood Pressure Education Program, NHLBI, 1979.

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE
NATIONAL CANCER INSTITUTE

Evaluation of Health Message Testing Service

Definition and Description of Program

The development of media messages to inform the public of health risks and appropriate actions is an expensive task. It is imperative that evaluative information be obtained as early in the process as practical to assure that the messages will be maximally effective. The National Heart, Lung, and Blood Institute and the National Cancer Institute are jointly developing a system to evaluate health messages for their potential broadcast impact while the messages are in the less costly preproduction stage.

Evaluation Study Performed

Design of Study

The project, cosponsored by the National Heart, Lung, and Blood Institute (NHLBI), the National Cancer Institute (NCI), and the Office of Health Information Policy (OHIP), has developed and is testing a system to evaluate health messages in the preproduction stage. Such systems are not now widely used and would be a cost-effective answer to pretesting health education messages. NHLBI and NCI, with assistance from an expert working group, have taken the first steps to create a message testing system that would be useful in pretesting both Institute messages and those of related voluntary agencies. This project has selected and refined such a system, and is now testing a variety of health messages to establish a baseline for comparison. Messages for the initial testing period are solicited from prospective users, both Government and non-Government. This test period will provide a demonstration of the methodology and a projection of user costs. Adoption of message pretesting would assure that the limited amount of media time available for health education would be allotted to the most effective messages.

Results of Data Analyses

- The system can be used for several purposes, including improvement of a single message before final production, comparison of alternative messages for greatest potential for effective communication, and assessment of audience perceptions of finished messages for planning message campaigns.

- Highest-scoring messages reflect certain production techniques that increase audience attention and information recall.

- In addition to the broadcast messages that the system was originally designed to test, it is feasible to test printed health materials.

Implementation

- The message testing system is being expanded to test printed health materials. Guidelines for creating both print and broadcast health materials with strong communication potential are being developed through the experience gained.

- Various health organizations in addition to the Federal agencies have used the system, including the Connecticut State Department of Health, the American Cancer Society, and the New York Office of Mental Health.

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Evaluation of Studies and Inventory of Data Bases on the Effect of Emergency Medical Systems on Prehospital Cardiovascular Care

Definition and Description of Program

The recent decline in U.S. cardiovascular mortality is consistent and is in contrast to its marked, steady increase from World War II through the early 1960s. Many hypotheses have been proffered to explain this reduction: coronary risk factor reduction, public health education, high-risk patient identification, the advent of coronary care units, improved medical technology, improved antianginal drugs (propranolol, for example), increased use of antiarrhythmic drugs, and coronary artery bypass surgery. Despite many studies in each of these areas, there are no data to support any of these hypotheses. Some have attributed the decline in cardiovascular mortality rates to the introduction of prehospital mobile coronary care (MCC). The ultimate explanation for this decline in cardiovascular mortality is probably a complex set of interactions among all these factors, superimposed over a set of yet undefined epidemiological phenomena.

With public and Congressional interest in expanding emergency medical systems (EMS) as MCC, especially in view of a possible relationship between EMS and a declining cardiovascular mortality rate, NHLBI and the Department of Transportation initiated this project to analyze the information to date about the effectiveness of prehospital cardiovascular care.

Evaluation Study Performed

Design of Study

A contract was undertaken by researchers at Boston University with three objectives:

- To determine whether the available information is sufficient to judge the effectiveness of MCC, and is appropriate to assess the value, validity, and generality of the data on the effectiveness of MCC.
- To develop a conceptual model for evaluating MCC, including a minimum data set essential to evaluation.
- To design a sampling strategy for MCC evaluation, assessing the extent to which an evaluation may rely upon existing data bases and the need for additional Federal research to supplement present data collection activities.

The investigators performed an extensive literature review and developed a conceptual model (including data requirements) for emergency medical systems evaluation.

Results of Data Analyses

The literature related to prehospital cardiovascular care can be characterized as follows:

- A limited number of research publications in the field are found in numerous types of medical journals, primarily in the general medical (36 percent) and cardiology (16 percent) literature.
- Thirty-one percent of all principal investigators in the area of MCC research are based at medical schools, 27 percent are outside this country, and the remainder are distributed among a variety of organizations. Very little research emanates from the Federal agencies directly responsible for EMS research.
- Fifty-six percent of the publications do not cite funding sources. According to articles reporting sources of funding, the Federal Government supports 39 percent of research. The remaining 17 percent of articles cite funding from a wide variety of sources.
- The ambulance system, as opposed to the community, is almost exclusively the sampling frame for data collection on EMS.
- Only 39 percent (132) of the articles reviewed report effectiveness measures (outcome and/or process). The remainder are "state-of-the-art," anecdotal, or public relations articles.
- Of these "effectiveness articles," 53 percent concern cardiac-dedicated vehicles, almost exclusively used in Europe. It is difficult to generalize from the results of the studies done in Europe, given substantial differences in the overall medical care system between continents. Only 23 percent of the 132 articles deal with paramedics.
- Only 20 percent of the effectiveness articles report both outcome and process variables; it is impossible in the remainder of the articles to ascribe the effect of any outcome to a prehospital intervention.
- Only 2 percent of the effectiveness studies employ multivariate analysis, which is necessary to control for and explain the complexity of clinical events involved in prehospital coronary care.
- Morbidity as an outcome is rarely reported (16 articles).

Analysis of the 118 articles presenting outcome data developed "best estimates" for key parameters related to cardiovascular disease incidence and MCC impact including, for example:

- The incidence of acute cardiovascular events in the community: 1.5 deaths from primary heart disease per 1,000 population.

- The length of delay to definitive care: 50 percent in less than 30 minutes; 75 percent within one hour.

In-depth review of the "outcome studies" (articles emanating from paramedic-staffed MCC systems that report outcome data for patients with acute cardiovascular disease (ACVD)) resulted in the following conclusions:

- Mortality from ACVD measured in the emergency room grossly underestimates the mortality rates through hospital discharge. Little change in mortality rate is seen between hospital discharge and 3-month followup.

- Fifty to 75 percent of patients with ACVD still arrive at hospitals by their own means and bypass EMS systems.

- The mortality rate from the cardiac arrest prehospital phase remains high, 79 to 83 percent.

- Patient delay, and not ambulance response time or excessive demand on the ambulance system, appears to be the limiting factor in achieving better outcomes.

- The results from patients in ventricular fibrillation when found in cardiac arrest are somewhat better. The mortality rate is reported in the 70-75 percent range, even from those EMS systems with outstanding reputations for efficient organization.

- A number of studies employing quasi-experimental design suggest that paramedic programs have a favorable effect, though various methodological problems and the uniqueness of the system limit generalizations.

- Essentially no valid, randomized trial with paramedics versus EMSs has been carried out.

The data analyzed do not support the hypothesis that MCC programs have substantially contributed to the decline in cardiovascular mortality rates in this country, a conclusion based on the following factors:

- The decline in cardiovascular mortality rate antedated the advent of MCC programs in this country. The decline in cardiovascular mortality rate became apparent in 1970, though the enabling legislation for MCC programs was not passed until 1973.

- Currently only 73 of the 297 EMS regions in the country have advanced life support systems that include MCC programs. These programs vary in their level of sophistication, but more important, service only a small proportion of the American citizenry (probably fewer than 10 percent) at this time.

- Using the data available from the literature review and a series of "extremely optimistic" assumptions, an estimate of the number of lives saved from MCC is 4,688 patients.

The current data base is inadequate to provide a rational framework for the evaluation of MCC programs; process and outcome measures of care are limited. The availability of MCC data from the Federal Office of Emergency Medical Services (OEMS) was judged to be inadequate. Of 268 EMS areas reporting data, only 11 report quantitative information, a number too small for a meaningful analysis.

Although the OEMS data base can serve to improve the management efficiency of those programs, and the research establishment's efforts are deemed necessary to develop and test new MCC methodologies, neither provides the necessary data for planning and system development. For this, a sampling strategy for an ongoing national MCC evaluation is needed. The contractor recommended that a sampling frame be developed along four strata:

- Region--North, North Central, South, West
- Location--urban/mixed/rural
- MCC system--basic life support/advanced life support
- Medical center affiliation--present/absent.

Recommendations Resulting From Study

The investigators concluded their study with several recommendations:

- The proportion of studies emanating from EMS projects/organizations should be increased in order to increase the breadth of MCC research in more generalizable settings.

- Many more experimental studies in diverse settings are needed for the accurate assessment of the impact of MCC. Such studies should be done in systems employing emergency medical technicians (EMTs) as well as paramedics. Measuring the impact of MCC will require using the community as the unit of analysis as opposed to the ambulance population. These studies will have to be increasingly sophisticated in design and use of multivariate analysis of both process and outcome measures in order to enhance our understanding of the complex set of interactive events in an MCC system of care.

- A sampling frame should be developed along the four strata of region, location, MCC system, and medical care affiliation. It is clear that this effort needs to be a cooperative venture undertaken by at least four agencies: Department of Transportation, the Federal Office of Emergency Medical Services (under the Health Services Administration), the National Center for Health Services Research, and the National Heart, Lung, and Blood Institute.

- Standardized definitions of acute cardiovascular disease should be adopted, and should include a measure of severity. Outcomes should also be standardized. Proximate outcome parameters should be developed to monitor the effectiveness of prehospital intervention.

- The literature search should continue to be updated. The data reviewed in this study should be added to the Medlars data on MCC studies.

- More research needs to be based in the community, as opposed to highly selected, medical school-affiliated ambulance services. Research partnerships between communities and medical schools should be encouraged to optimize the strengths of each--the general service capacity of the community and the research/grantsmanship capabilities of the medical schools.

- Only research using standardized definitions and process/outcome (mortality and morbidity) parameters should be encouraged.

- Researchers should be encouraged and funded at high enough levels to examine MCC impact on the community at large, as opposed to restricting the data base to patients accessing the ambulance service.

- A minimum data set needs to be defined for each patient. Multivariate analysis controlling for these variables is essential.

Implementation

Recently published, the report is being disseminated to the EMS and cardiovascular research communities. As the most complete review of cardiovascular-related emergency medical systems impact to date, the report is intended to serve as a basis for decision-making for the several agencies involved in emergency medical systems as well as a guide to program design for the evaluation community.

Reference

M. W. Pozen, J. B. Mitchell, J. Lisberger, "The Effect of Emergency Medical Systems on Prehospital Cardiovascular Care - An Evaluation of Studies and an Inventory of Data Bases, jointly published by National Highway Traffic Safety Administration and the National Heart, Lung, and Blood Institute, April 1981.

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Evaluation of Progress in Hypertension and Pulmonary Research

Definition and Description of Program

In 1972, through the National Heart, Blood Vessel, Lung, and Blood Act, the mandate of the National Heart, Lung, and Blood Institute was increased in a number of research areas. The law specified that NHLBI was to plan and coordinate the attack on heart, blood vessel, lung, and blood diseases by developing a national program. The program developed involves many disciplines and organizations, and encompasses the full spectrum of biomedical research from basic laboratory studies through applied clinical research and its application to clinical practice.

Evaluation Study Performed

Design of Study

To evaluate the impact of the 1972 Act on research progress, a variety of approaches might be taken. In the past, most evaluations of scientific progress have relied solely on subjective judgements by eminent professionals. In recent years, there has been increasing interest in augmenting such judgements with more objective, quantitative measures of progress. Such measures may be developed from analyses of journal publications, using techniques referred to as "evaluative bibliometrics." In this evaluation project, bibliometric techniques were employed to assess progress in three research areas directly affected by the Act--Hypertension (HPT), Lung Structure and Function (LSF), and Chronic Obstructive Pulmonary Diseases (COPD). Comparison of HPT, LSF, and COPD research activity in the years preceding and following passage of the Act, through the development and application of quantitative indicators, may assist the Institute in assessing the usefulness of bibliometric techniques for determining the effectiveness of its program.

Results of Data Analyses

- The bibliometric indicators reveal sharp differences between pre- and post-Act LSF and COPD publications, when compared with HPT. This result is consistent with the 1972 Act, which specifically targeted

LSF and COPD; whereas HPT had been targeted by earlier legislation. NHLBI also increased its support of frequently cited papers, indicating that NHLBI maintained the quality of its support while expanding its relative role in the field. However, the absolute rate of growth in papers in the targeted fields-at most, a few percent/year after the Act--was not as rapid as expected, because other support agencies were withdrawing support from the targeted fields at the same time that NHLBI was increasing its support.

- NHLBI was the largest acknowledged support source for all three fields before the Act, receiving 37, 25, and 23 percent of the U.S. support acknowledgments before the Act in HPT, COPD, and LSF. After the Act, the percent of U.S. acknowledgments to NHLBI in HPT was still 37, while COPD and LSF rose to 33 percent and 39 percent, respectively.

- As the roles of other agencies faded, NHLBI not only increased its role, but also appeared to be picking up a notable fraction of the frequently cited papers. Even in the pre-Act period the papers supported by NHLBI were cited approximately 30 percent more frequently than other papers in the field. However, in the post-Act period, when the NHLBI role was expanding, the difference in citation frequency between NHLBI and non-NHLBI papers was widening. In the period after the Act, NHLBI-supported papers were cited 50 percent more frequently than other papers in the field; further, 20 percent or more of the NHLBI-supported papers were in the top decile of cited papers, indicating a particularly high concentration of NHLBI support among the most frequently cited papers in the field.

- Also associated with the increased NHLBI activity was a shift toward more basic research in the targeted fields. The NHLBI-supported papers, even before the Act, were appearing in more basic journals, on the average, than were non-NHLBI papers. After the Act, all the papers in the fields seem to be trending toward more basic journals, with the NHLBI-supported papers trending particularly notably toward the most basic journals.

- For hypertension, the NHLBI role did not change in the post-Act period. The fraction of papers acknowledging NHLBI support was relatively constant, pre- and post-Act, and while NHLBI-supported papers were cited considerably more frequently than other papers in the field, this was true throughout the time period analyzed.

- The rate of growth of the literature in hypertension was considerably more rapid than in the other two fields; this rapid rate of growth, which was apparent before the Act, continued after the Act. Although the funding data are incomplete, this HPT growth appears to correspond to a much more rapid increase in funding for hypertension than for the other two fields.

- More than half of the papers in the fields studied that acknowledged NHLBI support also acknowledged support from other sources. In the area of hypertension, the leading cosupport source was the American Heart Association.

- The content analysis of the papers in all three fields seems to reveal a rather steady shift in emphasis from more general studies toward the more precise identification and characterization of specific substances; e.g., toward elucidating the roles of angiotensin/renin in HPT, alpha 1-antitrypsin in COPD, and pulmonary surfactant in neonatal RDS during the post-Act period. NHLBI-supported research appears to lead other supported research in this increasingly detailed analysis throughout all three of the areas.

- In general, the phenomenon observed seems to indicate that NHLBI is intensifying its role in the targeted field, both in the fraction of papers supported, and in support of frequently cited papers. However, this broadened and intensified NHLBI role was not enough to overcome the general pullback of research support, which began in the beginning of the decade and was still occurring in the post-Act period.

Implementation

- The evaluation study demonstrated that bibliographic methods can be useful in the analysis of detailed research programs. The methods are under consideration as part of the NHLBI 10-year review and update of its national plan.

- The results reinforce the Institute management strategy of identifying research needs and focusing support efforts on areas of most critical importance.

Reference

S.R. Reisher and F. Nari, "Bibliographic Methods for the Evaluation of Trends in Pulmonary and Hypertension Research," Computer Horizons, Inc., May 1980.

NHLBI 79-306

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Evaluation of the Factors Behind the Decline in Coronary Heart Disease Program

Definition and Description of Program

Coronary heart disease mortality, the Nation's leading cause of death, rose steadily from 1900 to the mid 1960s. At that point the trend reversed, falling over 20 percent during the past 15 years. Many factors have been proposed as causes for the decline, including increased hypertension awareness and more aggressive hypertension treatment, emergency medicine, and improved treatment methods. In its role as the lead agency for cardiovascular disease research, the National Heart, Lung, and Blood Institute held an evaluation conference to identify the possible factors and programs that relate to the decline and to chart a course for future research.

Results of Data Analyses

- The decrease in coronary heart disease mortality is real and not a result of artifacts or changes in disease coding.
- Primary prevention (through changes in diet, blood pressure, smoking, and other risk factors), as well as fundamental and clinical research leading to better medical care, has probably contributed to, but does not fully explain the decline.
- Precise quantification of the causes requires further study, especially to document changes in the frequency of nonfatal coronary events.

Implementation

The National Heart, Lung, and Blood Institute has taken steps to:

- Improve information on changes in the causes of death in cooperation with NCHS and the Census Bureau, by testing a methodology to combine the National Death Index with Census Bureau data.
- Refine the measures of risk derived from the Framingham and other epidemiologic studies through followup of the National HANES cohort, using 1980 census data.

- Study, using analytic methods, the changes in risk factors over the past several decades and their correlation with changes in mortality figures.

- Continue research on noninvasive measurement methods for arteriosclerosis, one of the prime risk factors for coronary heart disease.

- Initiate a project to gather data prospectively on changes in arteriosclerosis through autopsy.

- Study the feasibility for large-scale community surveillance programs to monitor risk factor changes over time and correlate these changes with morbidity and mortality.

Reference

Proceedings of the Conference on the Decline in Coronary Heart Disease Mortality, National Institutes of Health, NIH Publication Number 79-1610, May 1979.

NHLBI 79-307

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Evaluation of the Coronary Prone Behavior Program

Definition and Description of Program

During the past decade there has been increasing research interest in the impact of the so-called coronary prone behavior pattern on cardiovascular disease. Much of this research has been supported through the National Heart, Lung, and Blood Institute, which has recognized the need for a comprehensive, impartial, and objective review of the research. This evaluation studied the efficacy of the research to date and its relevance to the prevention and control of coronary heart disease, and developed recommendations for future research in the field.

Evaluation Study Performed

Design of Study

The project was carried out in two stages. During the first phase, the Forum on Coronary Prone Behavior, researchers compiled the most cogent data supporting the relationship of Type A behavior to coronary heart disease. As the second phase, the NHLBI sponsored the review Panel on Coronary Prone Behavior and Coronary Heart Disease. A panel of biomedical and behavioral scientists (cardiologists, epidemiologists, cardiovascular physiologists, psychologists, biostatisticians, soçiologists, and psychiatrists) evaluated the Proceedings of the Forum on Coronary Prone Behavior and all other available data related to Type A behavior and coronary heart disease. Five review panels were formed to evaluate the following areas: (a) the association of behavior and coronary heart disease; (b) the assessment of coronary-prone behavior; (c) the physiologic mechanisms underlying this presumed relation; (d) cultural and developmental patterns associated with the behavior pattern; and (e) intervention strategies. Each review panel was charged with the task of critically assessing the strengths and shortcomings of theory and research data in its assigned area and of providing recommendations for future research directions.

Results of Data Analyses

- An association exists between the popularly known Type A behavior pattern measurement instruments and coronary heart events, although clarification of the behavior and the reproducibility of the instruments is needed.

- Studies to date have not distinguished between the types of coronary heart disease and generally apply only to a demographically restricted population (males, over 39, upper-class). Future studies should broaden the range of study populations.

- Further evidence of cross-cultural validity is necessary to establish the extent to which the Type A personality is predictive of coronary heart disease.

- The primary causative role of Type A behavior in the development of coronary arteriosclerosis has not been established.

- Current information is insufficient to justify the use of therapeutic interventions in Type A behavior by clinicians.

Implementation

- A report from the evaluation was published in the journal Circulation (June 1981).

- Current research management in the National Heart, Lung, and Blood Institute has been restructured along many of the recommendations, in particular, the need to move the field toward more rigorous investigative methodology.

NHLBI 78-1

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Six-Year Followup Survey of Hypertension Public Knowledge and Self-Reported Behavior Vis-a-Vis High Blood Pressure

Definition and Description of Program

Hypertension affects some 60 million Americans and is a major factor in cardiovascular disease. In 1973, the newly launched National High Blood Pressure Education Program (NHBPEP) conducted a baseline survey of hypertension awareness, knowledge, and self-reported behavior. The purpose of the survey was to set program objectives toward combating this condition through a nationwide public and professional education program. In 1979, a followup study was performed, using a random sample of 5,000 Americans to assess program progress and to assist in revising the program objectives and strategy.

Evaluation Study Performed

Design of Study

The survey design consisted of a nationwide sample of 5,043 Americans, including an oversample of black Americans. During in-person interviews, the participants were asked more than 100 questions with regard to their knowledge of hypertension; their information sources; screening, treatment, and compliance experience; the effect of hypertension on lifestyle; and the effect on families of hypertensives. The data were analyzed and compared with the results of the 1973 survey.

Results of Data Analyses

Between 1973 and 1979 considerable progress was made in public awareness and knowledge of hypertension.

- Salt is now recognized as a factor in elevated blood pressure, and diet is identified as a potential control strategy;
- The sequelae or consequences of hypertension are more readily identified; high blood pressure is considered one of the most serious chronic medical conditions;

- Allied health professionals are more frequently noted as involved in hypertension detection and treatment, one of the major objectives of the NHBPEP;
- Gains in knowledge in the black community are larger in general than for whites, important because of the higher incidence of hypertension in blacks;
- Drug treatment is recognized by more persons as the most effective hypertension treatment;
- Knowledge of blood pressure readings and their implications has increased;
- Tension and anxiety continue to be associated with hypertension, despite efforts to point out that hypertension has no obvious symptoms;
- The need for hypertensives to remain on treatment is more frequently noted than in 1973;
- Self-reported compliance with therapy has not shown an increase but remains at a level requiring improvement.

Implementation

In response to these findings, the NHBPEP is in the process of

- Modifying its program objectives to emphasize the need for treatment compliance;
- Reformulating its media messages toward increased compliance;
- Developing materials for physicians and the public that take advantage of the increased public knowledge and emphasize the need to remain on treatment.
- Disseminating finds to local programs to assist in planning local educational efforts.
- Pursuing research to determine more clearly the relative impact of mass media upon the variety of professionals involved in hypertension control.

Reference

"The Public and High Blood Pressure: A Second Look. Six Year Follow-up Survey of Public Knowledge and Reported Behavior (DRAFT)," National Heart, Lung, and Blood Institute, March, 1980. Final report published September, 1981.

NHLBI 80-305

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Compliance with Hypertension Treatment Regimens: An Evaluation of the National High Blood Pressure Education Research Program

Definition and Description of Program

In 1972, the Secretary, HEW, established the National High Blood Pressure Education program to increase public and professional knowledge about high blood pressure and thereby facilitate biomedical management of the disease. The National Heart, Lung, and Blood Institute was designated as the coordinating Institute.

During the early years, four task forces dealt with establishment of standardized definitions and data bases for hypertension diagnosis and treatment, professional education, community education, and evaluation of the nationwide impact of the program. The task forces recommended that the Institute support a national education research program. This program, known as the National High Blood Pressure Education Research Program, emphasized development and delivery of cost-effective ways to educate professionals and the general public about hypertension, and sought research which would result in a better understanding of (a) the characteristics of an individual that relate to adherence behavior, and (b) educational interventions that enhance a patient's initial long-term adherence to antihypertensive therapy. The Education Research Program was implemented in 1973 and 1974 with the publication of two program announcements inviting the scientific community to submit research proposal applications in these areas. As a result of this initiative, 11 grants were funded by the Institute. By 1979,most of the grants funded by the program were complete. In addition, the field of compliance had grown tremendously and had produced a large data base of research findings and implementation activities. The Institute felt it was an appropriate time to evaluate the results of the research program.

Evaluation Study Performed

Design of Study

The project was carried out by an evaluation team of scientists and researchers selected to provide the necessary multidisciplinary expertise.

The team included clinicians, medical sociologists, health psychologists, and a bioethicist. The team was to develop a document that would (a) identify the major themes and summarize and put into perspective the large body of data resulting from the Education Research Program studies; (b) assess and evaluate key trends emerging from the rapidly growing field of compliance research; and (c) summarize generic issues and formulate recommendations for research and practice.

Results of Data Analyses

The evaluation findings review results of the 11 NHLBI funded compliance research projects published to mid-1980. In addition, these reviews are incorporated into the broader scientific literature on patient compliance to provide the reader with an up-to-date perspective on patient compliance with antihypertensive treatment. The reviews address the theory of compliance behavior; the measurement of compliance; strategies for improving compliance; in-depth analyses of two important and rapidly developing areas, namely, the role of the patient-clinician interaction and of social support; the state of implementation of compliance management strategies in public and private practice; and ethical concerns raised by the monitoring and management of patient compliance. In addition to a thorough assessment of the current state of the art for its topic, each review, where appropriate, also provides expert opinion on further research that is required or desirable and recommendations for practical implementation of existing knowledge.

The evaluation drew several key conclusions from the research:

- That the "active patient"--the patient involved in his own therapy--holds promise for improving compliance and blood pressure control.
- That the shifting of greater responsibility to the patient for his treatment may be the reason for improved compliance with therapy.
- That social support strategies involving home visitation are highly effective, regardless of whether the visitor is a trained lay person or a professional health educator.
- That three intervention themes, namely rewards for compliance, fear arousal, and patient instruction, did not prove to be very useful in improving blood pressure control and compliance outcomes. The review also concluded that the most useful product of the evaluation would be a document that incorporated the results of the Education Research Program with the results of other past research. The format of the final report follows this recommendation.

Implementation

- The evaluation report promises to be a valuable resource to groups within NIH as well as to the clinical and research communities. It should serve to inform the various advisory committees and initial review groups who plan and/or review behavioral and educational research

related to hypertension control, as well as clinicians, health educators, and behavioral scientists. The scope of the report is broad. It has the potential to stimulate activity over a wide range of the research/clinical applications spectrum.

- To date there have been a strong positive reaction to the findings and heavy demand for the report, which is in its second printing. At this point, however, it is still too early to determine the effect on research directions or on the clinical community.

- The findings are now being used by the National High Blood Pressure Education Program in the program of health education for both the general public and the health care delivery community.

Reference

Patient Compliance to Prescribed Antihypertensive Medication Regimens: A Report to the National Heart, Lung and Blood Institute, NIH Publication No. 81-2102, October, 1980.

6

NATIONAL EYE INSTITUTE

Dr. Carl Kupfer, Director

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Proposed Budget

		Dollars in Thousands FY 81	FY 82	FY 83
NEI 80-301	(amended) Analysis of NEI Program Evaluation and Planning Process	(5)	--	--
NEI 80-306	Third Formal NEI Program Evaluation and Planning Process	60	60	--
NEI 80-401	Tracking System for Implementation of Vision Research--A National Plan: 1978-1982	--	--	--
NEI 80-404	Feasibility Study of Evaluation of NEI Core Centers	--	--	--
NEI 82-301	Design of an Information System for Use in Evaluating the Implementation of the NEI 1983-87 Program Plan	--	100	--
NEI 82-302	Evaluability Assessment of the Cooperative Cataract Research Group	--	60	--
NEI 82-303	Evaluation of NEI Program Analysis System	--	75	50
	Total FY 82 Set-Aside Fund Request		$295	

Overview of Institute Evaluation Strategy

Policy Overview

Seven years ago the National Eye Institute began comprehensive program evaluation and planning. Three principal factors set the stage for formal evaluation and planning at the NEI: first, uncertainties concerning the annual level of Federal support of biomedical research; second, the need to evaluate program performance and determine program priorities to ensure the best allocation of scarce resources and establish accountability to the American public for the prudent expenditure of tax dollars; and third, the importance of having a rational basis upon which to determine the appropriate level of future Federal support for vision research.

Over the past seven years, the NEI in collaboration with its senior advisory body, the National Advisory Eye Council, has published two major national evaluation and planning documents for vision research. A two-volume planning report was published in 1975, an interim report incorporating updated program data was published in 1976, and a second comprehensive planning and evaluation effort culminated in a three-volume report that was published in 1978. This effort has entailed an evaluation of the entire NEI program, as well as an assessment of all identifiable vision research supported by other organizations in the United States. In developing these evaluation and planning reports, the NEI staff and panels of experts in the field of ophthalmology and vision research analyzed a large amount of data relative to such support.

The Office of Program Planning and Evaluation initiates the development of the annual NEI evaluation plan. A review session is held each year with NEI program heads from the intramural, extramural, biometry, and OD staffs to discuss their proposals for evaluation projects. After final selection of projects is made, a draft plan is reviewed by appropriate senior members of the NEI staff. Based on this session and review with the Director, NEI, the final document is prepared and sent to the Director, NIH.

Requests for proposals engendered by the evaluation plan and the resultant technical proposals are reviewed by ad hoc panels of experts, the composition of which is determined by the particular subject matter of the project under consideration. The NEI staff attempts to have the same groups review the progress reports and final drafts developed by those carrying out the project.

The information resulting from such evaluations is used to make policy and program management decisions at the NEI and to plan the allocation of available research resources to the areas of greatest need, importance, and research opportunity. This is especially important because of the plethora of opportunities for productive research and the limited funds and manpower to carry them out. The response to the NEI evaluation and planning efforts from the scientific community, the Congress, and the general public has been very positive. It is, however, the goal of the NEI staff to make our planning and evaluation process more systematic and more representative of the communities that the NEI serves.

At the present time, the NEI is in the process of updating the NAEC's program evaluation and national plan that was published in 1978. Later this year we will produce a multi-volume document that will redefine NEI program objectives, track progress toward meeting program goals, address the current needs and opportunities in vision research, and establish new or updated program priorities for the years 1983 through 1987.

Major Projects Underway or Recently Completed

No evaluation projects have been completed since publication of the FY 1981 NEI Evaluation Plan. However, the project, NEI 80-403, Evaluation of the Effectiveness of NEI Program Announcements in Achieving Institute Goals, has been dropped. This project called for the use of $5,000 in FY 1980 funds contributed by the NEI's own OD Management Fund and was to be carried out in-house. However, the NIH has instituted a procedure that renders this project virtually unnecessary and the NEI has, therefore, decided not to pursue it. A box has been included on the form used by prospective NIH grantees so that they may indicate whether their projects are submitted as the result of a program announcement.

The project, NEI 80-301 (amended), Analysis of NEI Program Evaluation and Planning Process, has been accomplished in two stages: the first phase of this project includes a history and description of the NEI's comprehensive program evaluation and planning activity; the second phase includes an assessment of NEI evaluation and planning strategy and process up through the development of the last five-year plan.

The project, NEI 80-305, Feasibility Study of Evaluation of NEI Core Centers, is also underway. It is being carried out in-house and will cost an estimated $10,000, which has been budgeted within the NEI's own OD Management Fund. This exploratory evaluation will provide information about the performance of core grants and their effectiveness as a vision research support mechanism. With information related to 25 active core grants, informed decisions may be made about the future of such centers in terms of their cost effectiveness and the percent of the NEI budget to be used for this type of award.

The project, NEI 80-306, The Third Formal NEI Program Evaluation and Planning Process, is also underway. During the past two years the staff of the National Eye Institute, aided by 250 consultants expert in the field of vision research, has evaluated the five programs supported by the Institute. This effort has entailed an evaluation of the entire NEI program, as well as an assessment of all identifiable vision research supported in the United States. In the development of these ongoing evaluation and planning reports, a very large amount of data has been analyzed by NEI staff and panels of experts. We expect to produce by the end of this year a multi-volume document that redefines NEI program objectives, tracks progress toward meeting program goals, addresses the current needs and opportunities in vision research, and establishes new or updated program priorities for the years 1983 to 1987. Cost estimates for FY 1981 and 1982 are $60,000 each.

New Projects Proposed

Project Title: Design of an Information System for Use in Evaluating the Implementation of the NEI 1983-87 Program Plan

Description: As a component of the comprehensive evaluation and planning activity of the National Eye Institute we intend to evaluate the implementation of our new national plan scheduled for publication this winter. Included in this project will be the project NEI 80-401 Tracking System for Implementation of Vision Research--A National Plan: 1978-1982, which was approved in the NEI FY 1980 Evaluation Plan for in-house funding and is underway. As a part of the evaluation of this implementation we would like to develop further our computer-based system that compares incoming grant applications and funded grants with our national plan's recommended levels of support in each priority area. The expanded system should show not only what correspondence there is between the subject matter of grant applications and program priorities but how well such applications fare in the review and funding process and what discrepancies there may be between submission of applications and funding in priority areas. We would also like to evaluate how well the plan's recommendations are carried out by means of measurements such as progress reports, citation analysis, bibliometric studies, and other ways to judge the outcome of NEI-supported research projects. The cost estimate for developing this system is $100,000 for FY 1982.

Project Title: Evaluability Assessment of the Cooperative Cataract Research Group (NEI 82-302)

Description: We would like to assess the evaluability of the Cooperative Cataract Research Group (CCRG), a component of the cataract program. This is a consortium of over 20 participating laboratories involving more than 100 investigators who have agreed to coordinate their efforts so that progress in research on the human lens and cataracts may be accelerated. Each laboratory participating in the CCRG has been assigned specific research tasks. We wish to determine what data are necessary and what methods should be used to evaluate this cooperative endeavor that focuses on a particular research problem to see if it has been successful in achieving its goals and whether it can serve as a model for attacking other vision-related clinical problems. The cost estimate for this evaluation project is $60,000 for FY 1982.

Project Title: Evaluation of Current NEI Program Analysis System (NEI 82-303)

Description: Since its inception, the National Eye Institute's computer-based program analysis system has been a reliable source of vital program information. The purpose of this project is to evaluate the manner in which this system has operated in the past and suggest improvements that will make the existing system more efficient and help integrate automated data management into virtually every major operation of the NEI, particularly program planning and evaluation, administrative management, budget, and scientific administration. Cost estimates for this project are $75,000 for FY 1982, and $50,000 for FY 1983.

NATIONAL EYE INSTITUTE

Evaluation of Program Planning at the National Eye Institute

Definition and Description of Program

Seven years ago the National Eye Institute began comprehensive program evaluation and planning. Three principal factors set the stage: first, uncertainties concerning the annual level of Federal support of biomedical research; second, the need to evaluate program performance and determine program priorities to ensure the best allocation of scarce resources and establish accountability to the American public for the prudent expenditure of tax dollars; and third, the importance of having a rational basis upon which to determine the appropriate level of future Federal support for vision research.

Over the past seven years, in collaboration with its senior advisory body, the National Advisory Eye Council, the NEI has published two major national evaluation and planning documents for vision research. A two-volume planning report was published in 1975, an interim report incorporating updated program data in 1976, and a comprehensive three-volume planning and evaluation report early in 1978. This effort has entailed an evaluation of the entire NEI program, as well as an assessment of all identifiable vision research supported by other organizations in the United States. In developing these evaluation and planning reports, the NEI staff and panels of experts in the field of ophthalmology and vision research analyzed a large amount of data relative to such support.

Evaluation Study Performed

Design of Study

This study was performed in response to a need to compile in a single document important information relating to NEI program planning and to provide an analysis of that planning effort by an independent source. The contractor interviewed members of the NEI and NIH staffs, past and present members of the National Advisory Eye Council, and NEI grantees and consultants. The contractor also obtained data from previously published planning documents and unpublished materials in NEI files.

Results of Data Analyses

The resulting analysis of program planning at the NEI focuses on the development of the first National Plan and assesses the current status of the NEI program planning process. It presents background on the economic and political situations that led to a formal planning process. The report discusses who was responsible for the plan, the processes used, specific recommendations and resource requirements suggested by the participants, and their subsequent implementation and tracking by the staff of the NEI.

Recommendations Resulting From Study

The recommendations called for:

- Studying the information and recommendations generated by the National Plan in order to use the material to optimal advantage in further developing the vision research program and determining future program and program planning needs.
- Developing an implementation plan to assign responsibilities for efficiently and effectively implementing the plan and documenting its implementation.
- Assessing NEI research programs in terms of stated program objectives.
- Assessing the NEI vision research program as a whole, thus integrating the assessments of the individual programs carried out to date.
- Refining and updating the NEI program planning rationale developed in 1973.
- Using principal investigators engaged in vision research in the program planning process, particularly in establishing program objectives, reviewing the priorities identified in the plan, and commenting on their use of the document.
- Distributing an overview of the plan to American and foreign clinicians to inform them of the state of the art of vision research in this country.
- Including an administrator and manager as consultants on future plans.
- Not designating future plans as reports of the National Advisory Eye Council.
- Initiating formal evaluations of each of the five major research programs of the NEI, using the plans as the foundation.

Implementation

Because this report was finished earlier this year, there has not been enough time for its assessment and recommendations to have affected NEI policy. Some recommendations were moot because they were for actions already taken in the production of the 1983-87 plan. Others were deferred for consideration in the next planning cycle.

NATIONAL EYE INSTITUTE

Evaluation of the National Eye Institute Core Grant Program

Definition and Description of Program

The NEI Core Grants for Vision Research Centers support central resource activities associated with research already under way and funded under individual research grants. The four primary objectives of this core grant program were stated in 1975:

- To afford NEI-supported investigators greater opportunity and flexibility for integrating common requirements for research resources;
- To enhance research capabilities and productivity by strengthening the research environment;
- To facilitate multidisciplinary approaches to specific problems in the visual sciences; and
- To promote interaction and collaboration between vision researchers and scientists in areas outside the visual sciences.

Evaluation Study Performed

Design of Study

In March 1980, an evaluation of the NEI Core Grant Program was initiated to study the implications of possible large-scale growth of this program and make recommendations with respect to its financial and programmatic impact on the overall NEI research grant program and to examine reduction of possible negative impact. A group of NEI staff and members of the National Advisory Eye Council and Vision Research Program Committee met to study the performance and effectiveness of over a score of ongoing core grants. They made informed decisions about the future of such centers in terms of cost effectiveness and the percent of the NEI budget to be used for this type of award. The study group redefined the objectives of the Core Grant Program and decided how those guidelines might be improved.

Results of Data Analysis

The evaluation showed that, based on the average dollar level of current

core grants and the current eligibility criteria, the percentage of the total NEI research grant budget obligated for core grants could have escalated to 20 percent by 1981 or 1982. It also indicated that a high percentage of the total core grant budget was being expended for administrative costs and salaries for new investigators; that pilot project costs were being borne by core grants when other support mechanisms were available for these purposes; and that the core grant program's objectives were too broad. The study group made specific recommendations to redefine these objectives and to limit the growth of the program.

Implementation

As a result of this evaluation, a new set of guidelines for the Core Grant Program was developed and published in June 1980. These guidelines included the following changes in response to the above findings: the allowable costs are more restrictive, the maximum direct cost that may be requested is $750,000 over five years, support is no longer provided for pilot studies or for adding new investigators, administrative costs may not exceed 15 percent of the direct costs each year, and the eligibility criteria are more restrictive.

The new objectives of the program were more clearly and precisely defined. They state that it is the purpose of this program (1) to afford groups of established investigators greater collaborative research capability by providing them with shared research resources, and (2) to attract scientists of diverse disciplines, including both clinicians and basic scientists, to vision research and to foster their interaction and collaboration.

Effects of Programmatic Changes

As a result of this evaluation project and implementation of the new guidelines, the portion of the NEI research grant budget obligated for core grants was held to 4 percent for 1981. In addition, the experience of NEI staff, applicants, reviewers, and members of the National Advisory Eye Council indicates that the revised guidelines have expedited the application and review process. Applicants and reviewers alike report that the new guidelines clearly state the criteria for a core grant, the format by which the application should be prepared, and the review procedures. Staff and reviewers find that deliberations during the study section and Council review are less protracted and the time required for discussion is greatly reduced. Because postaward management is within the revised guidelines, NEI staff has found less variability in utilization of this funding mechanism.

NATIONAL EYE INSTITUTE

Evaluation of the Implementation of the NEI Program Plan

Definition and Description of Program

In 1975, the National Advisory Eye Council issued its first program planning report, Vision Research Program Planning, identifying the major needs, opportunities, and priorities in ophthalmology and vision research by analyzing those critical areas of research in which there was adequate NEI support and those in which there was little or no support. Several recommendations were made for implementing the report's findings. In general, however, the Council assumed that the research community would respond voluntarily to the report in a positive manner and that significant shifts in program emphasis would occur as a result of individual scientists developing grant proposals for research identified as high priority in the report without need for directed programming by the NEI.

Evaluation Study Performed

Design of Study

The evaluation sought to analyze the impact of these recommendations on NEI grants during FY 1975 and 1976, as well as on grant applications recommended for approval but not funded and on those disapproved during FY 1975 and 1976. The evaluation also sought to determine the attitude of the research community toward the NEI program plan. Once this was accomplished, the needs and priorities identified in the 1975 planning report were reevaluated.

To carry out the evaluation, the National Advisory Eye Council reconvened its Program Planning Subcommittee and established under it five ad hoc panels of experts from the extramural community, one for each of NEI's five disease-oriented programs. To aid in performing the evaluation, the Council prepared an interim report in 1976 that summarized and reanalyzed data from another study (The Extent and Cost of Eye Disorders and Blindness, NEI 77-2) published earlier that year. This study was itself an analysis of available data on the incidence, prevalence, and cost of eye disorders and blindness, primarily to serve as a basis upon which to establish program priorities and develop rational program plans. It thus provided a valuable resource for the NEI's comprehensive program planning and evaluation activities. The effects of this data report were widespread. Since its publication all NEI

program planning panels have used it as a basis for determining program priorities. By providing an overview of the impact of visual disorders on the Nation, it has been important in helping establish criteria for subsequent NEI funding.

The panels analyzed grant applications recommended by study sections for approval but not funded, as well as those disapproved, to see whether there was any pattern in nonfunding of applications for support of research in areas of high program priority that had not received the highest scientific merit (study section) scores. In addition to the Program Planning Subcommittee and the disease-oriented panels, other members of the vision research community were queried informally regarding their reactions to the planning report and asked whether it would have any influence on the course of their research. Consultants were also asked for input on research needs and opportunities in specialized areas of vision science.

The subcommittee and panels reviewed the 1975 report and reevaluated its recommendations in terms of their own knowledge and experience in vision research and analysis of data pertaining to the current NEI portfolio of grants to determine what shifts in support, if any, had occurred toward those areas designated for emphasis. Specifically, in its 1975 planning report, the National Advisory Eye Council had accorded special attention to 24 research topics which, in its judgment and that of its consultants, were not only highly important to prevention, diagnosis, and treatment of visual system disorders but were also likely to be productive lines of inquiry. The panels of experts established to prepare the 1977 report attempted to draw definitive conclusions about the substantive impact of these recommendations on the course of vision research and the quality of eye care.

Results of Data Analyses

The panels made the following observations:

- Overall, NEI's current support of vision research clearly reflected the recommendations in the Council's first report. Of the net increase of 219 grant awards between FY 1974 and FY 1976 for all programs, 112 (51 percent) were in the 24 areas identified for special emphasis.

- In 9 of the 24 special emphasis areas, a substantial increase in level of activity occurred between FY 1974 and FY 1976, i.e., increases of from 59 percent to 367 percent. For these nine areas, it is apparent that the report reflected and reinforced emerging trends in vision research and possibly stimulated others.

- For Retinal and Choroidal Diseases, the largest of NEI's five extramural programs, there was a notable increase in the number of NEI-sponsored projects in six of the eight priority areas identified. Similarly, for Sensory and Motor Disorders of Vision, there was a major increase in the number of NEI-sponsored projects in three of the four priority areas identified.

This evaluation of the community's response to the planning report indicated what further steps were necessary to implement the recommendations of the first program plan and served as an important guide in preparing the second planning document.

Implementation

As a result of this evaluation, the second major planning report of the National Advisory Eye Council, Vision Research--A National Plan: 1978-1982, was published. Some of the Council's recommendations for improving NEI's comprehensive program planning and evaluation effort that were incorporated in the 1977 report included: creation of new subprograms that better defined the nature of research supported in all five NEI programs, specification for the first time of program goals and objectives, more detailed and comprehensive lists of program priorities, more thorough survey of extent of data related to the extent of the problem, more complete information from agencies and organizations other than the NEI that support vision research, and an improved report structure that emphasized the analytical and evaluative bases of the program plan. Volume One of this 1977 report contains a summary of the National Advisory Eye Council's evaluation of the NEI's vision research program, its recommendations for future program development, and a discussion of important cross-cutting policy and administration issues facing the National Eye Institute. Volume Two presents the complete reports of the panels of experts convened by the Council to assist in evaluation and planning of the NEI's research and research training programs. Volume Three presents extensive data on vision research supported in the United States, which served as an important and informative resource for the work of the panels and the Council.

In its first 1975 report, Vision Research Program Planning, the National Advisory Eye Council concluded that, for the most part, the direction and scope of vision research in the United States were oriented appropriately toward the needs of society. However, the council recommended some "modest redirection" of this effort in order to make vision research even more responsive to the public's desire for improved eye care and health. The National Eye Institute was advised to pursue this redirection by actively disseminating the Council's report to the vision research community and to the general public and relying upon individual investigators to initiate projects in the areas of need and opportunity which the Council identified. More vigorous methods of implementing the Council's recommendations, such as earmarking specific funds for awards in special emphasis areas, were judged not in keeping with the largely unpredictable pace and pattern of scientific advance and were therefore considered inappropriate.

In its second program planning report, published in 1978, the Counci reaffirmed its view that the NEI should in general continue its "gentle" approach to promoting research in accordance with identified priorities. However, the Council also believed that, in selected cases, it was now both appropriate and desirable for NEI staff to expand and intensify its implementation efforts.

Most important, this program plan was to be used by the National Advisory Eye Council and NEI staff as a basis upon which to make judgments of program relevance concerning individual grant applications. In addition, the following activities were to be undertaken:

- Publication in the widely read NIH Guide for Grants and Contracts and leading vision science journals of announcements that encourage investigators to submit grant proposals in specific areas of research.

- Organization and sponsorship of workshops, symposia, and other discussion forums in which particular vision research needs and opportunities can be defined further and made more widely known.

- Identification of high priority, clinically relevant research opportunities that can be best taken advantage of through the support of cooperative clinical trials and specialized clinical research centers.

- Support, through research contracts, of selected research resources such as animal model breading and distribution and instrumentation development and evaluation.

Effects of Programmatic Changes

As a result of the above implementation, there have been numerous announcements requesting grant proposals in important areas of research and several workshops, for instance, a series relating to the immunology of the eye. In addition, and perhaps most important, establishing a framework for the National Advisory Eye Council has provided guidance for Council actions on grant proposals given study section scores at the funding margin. Those areas determined by the Council to be in need of increased research activity have, in fact, seen increased grant applications, approvals, and subsequent funding. Thus, the portfolio of NEI-supported research has reflected the judgment of the best minds in the field of ophthalmology and vision research, and we can expect such research to bring about significant advances in prevention, treatment, and etiology of the major eye diseases and disorders of the visual system.

7

NATIONAL INSTITUTE ON AGING

Dr. Robert N. Butler, Director

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Proposed Budget

		Dollars in Thousands FY 81	FY 82	FY 83
NIA 79-301/3	Evaluation of NIA Animal and Cellular Resources Programs	194	--	--
NIA 79-302	NIA Research Management Information System	117	--	--
NIA 80-301	Evaluation of the Geriatric Medicine Academic Award Program	31	--	--
NIA 82-301	Development of a Systematic Procedure for the Monitoring and Review of Research Grant Progress Reports	--	50	--
	Total FY 82 Set-Aside Fund Request		$ 50	

FY 82 Evaluation Strategy Statement

The National Institute on Aging (NIA), established in 1974 by the Research on Aging Act, is mandated to conduct and support biomedical, social, and behavioral research and training related to the aging processes and the diseases and other special problems and needs of the aged. The NIA has established programs in biomedical research and clinical medicine; social and behavioral research; and epidemiological, demographic, and biometric research.

- The Biomedical Research and Clinical Medicine Program focuses on research related to the basic aging processes, physiological changes with age (such as immune, neural, and endocrine functions), and clinical problems (for example, nutrition, drug interactions and utilization, and the special medical problems of the aged).

- The Social and Behavioral Research Program supports research on the psychological and social aspects of aging as a process; the behavior, attitudes, and status of older people within a changing society; and the relationships between aging individuals and social institutions.

- The Epidemiology, Demography, and Biometry Program coordinates and conducts quantitative population-based research on health and disease in the aged, as well as demographic and economic analyses.

The NIA is currently engaged in the development of a National Plan for Research on Aging, with the assistance of a panel of scientists. This panel will advise the NIA in its formulation of a five-year strategy for promoting the health and well-being of the aged population through research into the biomedical, behavioral, and social aspects of aging. The broad objectives of the National Plan are to provide a stable, long-term framework for conducting research on aging; establish a sound, scientific basis for setting priorities; identify areas where interdisciplinary and multidisciplinary approaches offer the greatest promise; and identify opportunities in aging research which will attract scientists to the field.

Major Projects Underway

As a basis for developing the National Plan for Research on Aging, the panel will be provided with the results of an inventory of Federally supported aging research and training activities. The panel will also consider the findings of the Evaluation Panel for the NIA Genetic and Cellular Resources Program (NIA 79-301) and the Evaluation Panel for the NIA Animal Models Development Program (NIA 79-303) in making its

recommendations to the Director, NIA, regarding research resources required in the the upcoming years to implement the panel's recommendations for research on aging. The Reports of the Evaluation panels and the National Research on Aging Planning Panel will assist the Director, NIA, in making necessary scientific and administrative changes to improve the effectiveness and efficiency of the NIA Genetic and Cellular Resources Program and the NIA Animal Models Development Program.

The Evaluation Panels held their orientation meetings during February 1981, with final reports expected in April 1982. The evaluation of the NIA Genetic and Cellular Resources Program involves the assessment of the impact and effectiveness of the NIA program of selection, production, characterization, and distribution of genetic and cellular resources for the support of research on aging. The evaluation of the NIA Animal Models Development Program is intended to provide a comprehensive assessment of the effectiveness of the NIA program of supplying aged animals for the support of research on aging, and a determination of the relative efficiency of various alternatives for meeting the need for aging animal models. Each Evaluation Panel will make recommendations in a final report to the Director, NIA, about current and projected research resource needs and/or alternative means of meeting those needs.

The NIA Research Management Information System project (NIA 79-302) was initiated in FY 1980. This system will provide NIA with a scientific data base, enabling the quick retrieval of information regarding research projects and program balance and directions. The contractor for this project has begun to summarize NIA grants from FY 1978 to the present. These summaries will be coded to correspond to a taxonomy on scientific content which was recently developed by the NIA.

Later in FY 1981, the NIA will begin to develop the methodological approach for the Evaluation of the Geriatric Medicine Academic Award Program (NIA 80-301). This award mechanism was established in 1978 for the dual purpose of improving the quality of curricula in geriatrics and fostering research and careers in the field of aging. The two general purposes of this evaluation are (a) to assess the overall impact of this award mechanism on the basis of predetermined measurable objectives of the program; and (b) to differentiate among various project and grantee institution characteristics, settings, and approaches in terms of indicators of success.

New Project Proposed

In FY 1982 the NIA proposes to undertake the Development of a Systematic Procedure for the Monitoring and Review of Research Grant Progress Reports (NIA 82-301) with evaluation set-aside funds. The primary basis for monitoring grants supported by NIA is the progress report submitted annually by the principal investigator. Program staff is becoming increasingly dependent on these reports to measure individual projects as well as to assess the effectiveness of research programs. Although there is heavy dependence on the progress report, there is not a systematic procedure throughout the NIA for the monitoring and review of these reports. The development of an Institute-wide system of assessment will enable a uni-

form framework for interpreting and measuring the success of NIA programs. The NIA is requesting $50,000 in set-aside funds in FY 1982 for the support of this project.

8

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Dr. Richard M. Krause, Director

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NIAID

Proposed Budget

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NIAID/NIH 80-302	Evaluation of Institutional Biosafety Committees (IBC)	--	--	--
NIAID 80-401	Evaluation of the Impact of the NIAID/ OMAR Consensus Development Conference on Amantadine	--	(3)	--
NHLBI/NIAID 81-303*	Education Programs and Materials for Self-Management of Children With Asthma	(49) --	55	28
NIAID 82-301	Evaluation of the NIAID Vaccine Development Program	(50)	440	--
	Total FY 82 Set-Aside Fund Request		$495	

*NIAID is cofunding this project with NHLBI

FY 82 Evaluation Strategy Statement. The mission of the National Institute of Allergy and Infectious Diseases (NIAID) is to support research on all infectious diseases and diseases of the immune system, including asthma and other allergies. The Institute also funds studies in the basic disciplines of immunology, bacteriology, virology, parasitology, and mycology. Because these scientific disciplines provide the fundamental knowledge applicable to missions of other components of NIH, NIAID-supported research often provides needed new knowledge to targeted efforts of Institutes oriented toward organ systems or specific disease entities.

The NIAID operates under an overall philosophy of relying on free-ranging research in microbiology and immunology and on clinical studies in allergy, immunologic, and infectious diseases. With the assistance of advisory groups of experts, important national health problems are identified, opportunities and strategies for prevention or treatment of important diseases developed, and advances in technology assessed. It is assumed that an increased research effort ultimately will aid materially in solution of these public health problems. Our advisory groups provide input for decisions regarding determination and structuring of Federal intervention in the research process directed toward the long-range goal of solving the health problems within the purview of the Institute.

In recent years the Institute has organized along programmatic, rather than mechanism of support, lines and by a twofold policy decision: a) to fund a core of investigator-initiated research based on scientific merit and b) to allocate remaining funds to program directors for specific activities judged by them and the National Advisory Allergy and Infectious Diseases Council (Advisory Council) to be ready for stimulation by Federal funding.

The two extramural programs - the Immunology, Allergic and Immunologic Diseases Program (IAIDP) and the Microbiology and Infectious Diseases Program (MIDP) both make use of a mix of mechanisms - research grants of various types, contracts, and training awards. The development of performance indicators and the design of evaluation studies will be linked to the substantive aspects of the science, to the mechanism of support, and to specific managerial needs. Performance indicators that would be valid for investigator-initiated research would not be the same as the performance indicators used to evaluate Institute-supported work in "applied" areas. The development of appropriate performance indicators and evaluation design will be necessarily tailored to the specific programs or projects that are being evaluated.

FORMAL PLANNING EVALUATION PROCESSES

The Institute planning and evaluation process draws heavily on a series of task forces and study groups which, in aggregate, cover essentially all Institute responsibilities. Budgetary and

programmatic changes are a result of in-depth staff analyses and Advisory Council decisions following review of recommendations of these groups.

The task forces and study groups that have been active over the last several years include the following:

1. Asthma and Other Allergic Diseases Task Force
2. Virology Task Force
3. Sexually Transmitted Diseases Study Group
4. Study Group on Immunology

Institute initiatives stem from these task force-study group reports and ensuing Advisory Council recommendations. The following are examples of this process:

Asthma and Other Allergic Diseases Task Force

During FY'79, the work of the Task Force on Asthma and Other Allergic Diseases was completed. The Advisory Council, after review of the conclusions reached by the task force, recommended that the budget for this program be increased from approximately $65 million in FY'79 to $118 million by FY'84 and recommended increased funding in 12 specific areas. These included:

Basic Mechanisms of the Immune System
Asthma
Hay Fever
Special Problems of Allergic Children
Drug Allergy
Epidemiological Studies of Asthma and Other Allergic Diseases
Allergic and Immunologic Aspects of Other Diseases
Research Training and Technology Transfer

The largest dollar increment recommended was for increased support for study of basic mechanisms of the immune system (from $47.9 million in FY'79 to $80.0 million by FY'84). This was based on the conviction that the understanding of basic mechanisms, in the final analysis, is most likely to lead to immunologic, pharmacologic, and other therapeutic modalities which can be used for prevention or cure of immunological diseases. Support for basic research crosscuts the entire efforts of the IAID Program. Three specific Institute initiatives which stem from the efforts of this task force are the following:

- Two new immunodermatology centers were established within existing asthma centers.

- A field trial is currently ongoing to evaluate the efficacy of skin testing with major and minor determinants of penicillin prior to prophylactic administration of this drug or its analogs.

- A contract is currently being negotiated for acquisition and standardization of allergens.

The Advisory Council recommended establishment of clinical investigator awards (K08), but due to budgetary constraints this funding mechanism has not been activated.

Virology Task Force

During the period of October 1976 through September 1978, the NIAID Task Force on Virology undertook an in-depth and comprehensive assessment of the state of the art of virology, identifying several key areas of scientific opportunity. The Advisory Council reviewed the task force report and recommended that the NIAID seek to double its investment in virus research over the next five years--expanding and emphasizing its efforts in 11 research areas. The research areas identified for expansion and emphasis included:

- Live virus vaccines and new and improved inactivated virus vaccines
- Development of antiviral drugs
- New techniques for detecting, isolating, and propagating viruses
- Mechanisms of persistent viral infection and their relationship to chronic disease
- Virus structure, multiplication, and use as research models.

The Microbiology and Infectious Diseases Program was, in fact, sponsoring research in all of the 11 areas covered by the Advisory Council recommendations. Program emphasis was, however, shifted in accord with Advisory Council recommendations. The following are selected examples of Institute initiatives resulting from the efforts of this task force:

- A contract has been let which will evaluate live attenuated varicella vaccine in high-risk children.
- Research efforts within the five general Vaccine Evaluation Centers have been expanded to include assessment of antiviral drugs (e.g., amantadine/rimantadine) in the prevention and treatment of influenza.
- A contract has been awarded to develop antivirals based on knowledge of the unique nucleic acid sequences of viruses, using influenza A as a model virus.

In addition, the Task Force on Virology Report provided essential background material for the NIAID Sexually Transmitted Disease Group Recommendations (March 1980) on herpes simplex virus, cytomegalovirus, and hepatitis B virus infections.

The NIAID also participates in two interagency groups that have a significant influence on several components of the virology research programs. The Interagency Work Group on Influenza is composed of representatives from the NIAID, BoB/FDA, and CDC, which serves as the lead agency. The group is charged with developing an influenza pandemic contingency plan which includes an annual determination of new variants, the likelihood of epidemic or pandemic potential, establishing the vaccine formulation, and decisions regarding field testing. A second activity concerns the Interagency Group to Monitor Vaccine Development, Production, and Usage and is involved with vaccines other than those for influenza. This latter group is composed of representatives of the NIAID, BoB/FDA, CDC, and the military and is responsible for monitoring the development, production and supply of vaccines in the United States.

* * *

The recommendations resulting from the efforts of the Asthma and Allergic Diseases Task Force and the Virology Task Force will continue to serve as a scientific guide and will have a significant impact on the Institute planning process. In future years, as the Institute more fully develops program performance evaluation studies, the impact of such task force efforts will be assessed.

* * *

Sexually Transmitted Diseases Study Group

The Study Group on Sexually Transmitted Diseases (STD) was established in FY'80, in part in response to Congressional interest. This group actively examined current research on sexually transmitted diseases. A subcommittee of the Advisory Council formulated recommendations to be considered by the full Advisory Council at both the May and September 1980 Advisory Council meetings. In September of 1980, the Advisory Council recommended that NIAID increase its support for research on genital herpes and cytomegalovirus and reaffirmed their initial view that a substantial increase in the training effort was essential to the development of a high-quality research program in sexually transmitted diseases.

As a result of these recommendations, there has been a substantial increase in research funding in the overall STD program, particularly for chlamydia, gonorrhea, herpes, and cytomegalovirus. Due to budgetary constraints, no increased funds have been allocated for training. In May 1981, Dr. King K. Holmes, Chairman of the STD Study Group, will present to the Advisory Council a progress report in STD since completion of the study group report. This will be the first progress report and a preliminary evaluation of its impact on the program.

Specific examples of Institute actions resulting from the efforts of this group are the following:

- Plans to expand Program Project Research Units (STD Centers) to a total of four if funds are available.

- The potential benefits of treating genital herpes with interferon are being investigated under a new contract awarded this year.

- Acyclovir, a new antiviral compound, has been shown to have potential therapeutic effects. NIAID is testing the efficacy and toxicity of this compound in animals, while a commercial drug house is evaluating the drug in patients.

Study Group on Immunology

The Study Group on Immunology which was initiated in FY'80, comprised six independent panels. The study group participated in a series of workshops to determine the state of immunological knowledge in those selected areas where important developments are most likely to occur, highlight opportunities for research in general terms, and suggest specific recommendations for pursuing these opportunities.

The final report of the Study Group on Immunology, New Initiatives in Immunology, was published in 1981. Six initiatives were identified by the study group for special emphasis:

- Cloning of immunocompetent cells
- Molecular genetic approaches in immunologic systems
- Regulatory mechanisms of the immune response
- Effector mechanisms
- The antigens of the major histocompatibility complex and their role in cellular interactions
- Hybridoma technology to produce monoclonal antibodies and the application of monoclonal reagents to biology and medicine.

After review of the conclusions reached by the Immunology Study Group, the Advisory Council has recommended increased research and training in all six areas.

Although this report has only recently been evaluated by the Institute, the following projects are planned as a result of the efforts of the task force:

- NIAID has issued a request for applications for Lymphocyte Biology Centers; it is hoped that two such centers will be supported in FY'82. New work in these centers will involve basic and applied research in immunology outlined in the study group recommendations.

- An RFP has been issued for the establishment of a reagent resource of antisera to mouse cell surface antigens known to be

important in immunoregulation and transplantation biology. Availability of these reagents will facilitate research in that field.

- A second RFP to obtain antisera against cell surface antigens important in functional differentiation of lymphocytes has also been issued. These reagents will be valuable to investigators attempting to dissect the elements of the immune response and understand the maturation of the cells involved. An ongoing contract for banking of hybridoma cell lines will allow investigators access to this important resource.

* * *

Budgetary constraints have not permitted full implementation of Advisory Council recommendations resulting from the efforts of these several task forces. In general, monies for new initiatives are obtained following phase-out of completed Institute-supported research.

* * *

U.S.-Japan Cooperative Medical Science Program

Each year, unless otherwise specified, two panels are reviewed according to format by a member of the U.S. Delegation and a member of the Japanese Delegation. Last year, the Cholera and Malnutrition Panels were formally reviewed. In July 1981 a review of the Leprosy and Parasitic Diseases Panel will be initiated. In addition, panel chairmen on both sides write annual reports of research progress for their particular disease category and these are reviewed by both the U.S. and Japanese Delegations. Approximately every five years, a comprehensive report of program progress is prepared. The Third Five-Year Report, 1975-1980, was published in September 1980 and has been widely distributed. Annual evaluations, in conjunction with the more formal five-year report, are useful evaluation documents aimed at the overall objectives of the program.

American Society for Microbiology Manpower Survey

In FY'79 this project was initiated by the American Society for Microbiology (ASM). Using the ASM membership as a population, the society has compiled and analyzed the status of member scientists whose activities are all relevant to the mission of the Institute. NIAID staff is currently working with ASM staff on the final study report, which will include analyses of the collected data from several vantage points. Efforts are in progress to extract more refined data cuts from the existing compilations. This analysis, when completed, will contain a large data base and should serve as a useful resource over the next several years to answer questions regarding NIAID training needs and the impact of budgetary constraints on such training.

Intramural

The NIAID Intramural Program is reviewed by a Board of Scientific Counselors. The purpose of the board is to provide an objective peer review of the relevance and quality of research being conducted within the Intramural Research Program. The scope of the review ranges from individual interviews of the scientific staff within a laboratory, including both tenured and non-tenured scientists, to analysis of scientific output of organized groups of scientists such as sections within a laboratory, and finally an evaluation of the laboratory in its entirety, including utilization of resources. The Board of Scientific Counselors consists of eight members who serve for a period of four years. The board, plus six ad hoc members, meets three times per year and reviews one to two laboratories during each review session; each laboratory is reviewed every three to four years.

Evaluation of the Institutional Biosafety Committees

In FY'80 NIAID initiated its first program performance evaluation--an Evaluation of Institutional Biosafety Committees (IBC). NIAID has lead Institute responsibility for risk assessment and the administrative responsibility for recombinant DNA research through the Office of Recombinant DNA Research Activities. The IBC committee structure is required of all institutions that receive Federal funds to support research programs using recombinant DNA technology. The IBC structure and responsibilities are outlined in detail in the NIH Guidelines for Recombinant DNA Research. This study was designed to evaluate the effectiveness of the committee format, including its mandated composition, and procedures and to develop recommendations for optimizing the balance of Federal and institutional roles to assure uniform levels of biosafety in the conduct of Federally sponsored research.

Phase I of the study included a major national meeting of the IBC chairmen on November 1980. During the meeting, a draft evaluation plan for Phase II was discussed for modification. Key recommendations that resulted from that meeting were:

First, that experiments currently covered by Section III-O of the NIH Guidelines be made exempt from the NIH Guidelines. The IBC chairpersons felt that the risks associated with these experiments are negligible, and that exemption of experiments currently covered by Section III-O would reduce paperwork by approximately 90%. This recommendation was discussed by the Recombinant DNA Advisory Committee (RAC) at its January 1981 meeting. An overwhelming majority of RAC members favored taking formal action that would materially reduce or eliminate the paperwork and reporting functions for experiments covered by Section III-O. The RAC requested that a series of options be developed and published for comment in the Federal Register. Accordingly, three options have been prepared and will be considered at the April 1981 meeting of the RAC.

The second key recommendation that resulted from the meeting was that Phase II of the study be broadened to include safety issues other than recombinant DNA. This recommendation emanates from the viewpoint of the large majority of IBC chairpersons that there are many larger issues on the horizon of concern to institutions (e.g., chemical carcinogens and etiologic agents) which are apparently more hazardous than recombinant DNA. Accordingly, NIAID staff is collaborating with the Director, Division of Safety, OD, in developing a revised approach to Phase II of the study.

Major Projects Underway or Recently Completed

1. Evaluation of the Impact of the NIAID/OMAR Consensus Development Conference on Amantadine

A study to evaluate the impact of the Consensus Development Conference on Amantadine for prophylaxis and treatment of influenza A infections was initiated in FY'80. This study is being coordinated with efforts of the Office for Medical Applications of Research to assess the impact of the NIH Consensus Development Program. IMS America has sent the first half of the prescription data to NIAID covering Phase I (the years 1977 through 1979--prior to the consensus meeting). The second half of the data from 1980 through 1982 (post-consensus meeting) will be forwarded to NIAID by IMS America in 1982. The data for all five years will be analyzed at that time and compared.

2. Evaluation of the Impact of the Joint NIAID/NHLBI/American Heart Association Consensus Development on Treatment of Streptococcus viridans Bacterial Endocarditis

This study was approved by DHHS as part of the FY'81 Plan. The study was designed to assess the impact of the conference recommendations on hospital days and medical complications of bacterial endocarditis prior to the consensus and several years later. NIAID staff has decided not to proceed with this project because of an unanticipated scientific publication which presented findings basically identical to the consensus findings--prior to promulgation of the formal consensus findings. Therefore, any reduction in hospitalization and length of therapy thus could not be clearly attributed to the consensus development when the recommendations are finally published. Staff has considered redesigning the study with a negative hypothesis; insufficient numbers of patients exist, however, for this latter study design. NIAID is, therefore, formally withdrawing this study at this time.

3. Evaluation of Education Programs and Materials for Self-Management of Children with Asthma

This study is a joint project between NHLBI and NIAID and was approved by DHHS as part of the FY'81 Plan. A number of Federal and non-Federal agencies have mounted programs to encourage and to improve the effectiveness of pediatric asthma self-management. This project will evaluate the results of these efforts to date, analyze the need for such programs and the health system resources required for such self-management, identify the most successful approaches, and outline future objectives and related progress measures for the several programs. Phase I of the project is underway and will include a workshop (June 1981) on Self-Management Educational Programs for Childhood Asthma. That workshop is a preliminary survey, which will have as its primary objective a review of the scope of available materials, analyses of various educational techniques, and if appropriate, will outline the performance indicators to be employed during Phase II of the evaluation.

New Project Proposed

Due to the multifaceted nature of the two major NIAID programs--Immunology, Allergic and Immunologic Diseases and Microbiology and Infectious Diseases--meaningful results could not be expected from attempts to evaluate these programs in their entirety. A breakdown of subprograms of MIDP and IAIDP, amenable to program performance evaluation studies, will be developed by staff and approved by the Director, NIAID. We anticipate being able to complete Stage I program performance evaluations on one-third to one-half of the MIDP and IAIDP subprograms by the end of FY'82.

1. Evaluation of the NIAID Vaccine Development Program (New Project)

This study will be a full-scale program performance evaluation of the NIAID Vaccine Development Program and is scheduled to begin in FY'81. This study will provide the data base for selection and sequential development of candidate vaccines for rapid development into clinical usage via the DHHS initiative on Accelerated Development of New Vaccines. The methodology of the study will be developed by staff of the Institute of Medicine, National Academy of Sciences, who will perform the study under contract, in response to the evaluation requirements established by NIAID staff. The study will be initiated using Institute funds in order that work on the evaluation can be undertaken in FY'81. The general approach to be used will involve the development and application of specific performance indicators sequentially to three categories of infectious diseases: 1) those of major importance to the U.S. population in general, 2) diseases of importance to specific groups within the U.S., and 3) those of primary importance to developing countries.

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Evaluation of the PHS-NIH Biomedical Research Training-Specific Allergy and Infectious Diseases Program

Definition and Description of Program

The National Institute of Allergy and Infectious Diseases conducts and supports research contributing to a better understanding of the causes of allergic, immunologic, and infectious diseases and to the development of better means of preventing, diagnosing, and treating such illnesses. A widely accepted and important way of assuring maintenance of momentum and further growth of knowledge is to ensure the continued existence of a knowledgeable and highly motivated manpower pool by supporting the training of young scientists and physicians with institutional and individual grants. In FY '80 NIAID supported a total of 522 FTE training positions at a cost of $9.6 million. Training in infectious diseases and associated areas of microbiology utilized 317 positions at a cost of $5.8 million. Because microbiologists perform this large portion of NIAID's research, data are needed to determine the manpower turnover, the length of service, the primary areas of research, etc. Information about these activities is expected to provide a better basis for judging training needs.

Evaluation Study Performed

Study Design

The purpose of this project was to collect data from American Society for Microbiology (ASM) members already employed or being trained in the various disciplines and subdisciplines of microbiology. Information was obtained on the educational background, age, sex, and other demographic characteristics of the members. The report identified employment sectors and characteristics, including the source of research support, and assessed the labor market status of microbiologists.

The study was based on a questionnaire survey of members of the ASM residing in the United States. The questionnaire was designed by ASM staff after consultation with statistical and computer consultants and NIAID staff and was finally modified following a pretest. The questionnaire was distributed to 25,891 members. Of those returned, 15,665 (60.5 percent) were included in the analysis.

Results of Data Analyses

The following partial list of major findings illustrates the information that can be extracted from the data collected:

- Of the five employment sectors used in this study, almost half of the respondents (43.8 percent) report academia as their current primary employer.
- Approximately 34 percent of all respondents work in basic and applied research.
- Student respondents appear to be concentrated in eight specialty fields: general microbiology, clinical/medical microbiology, bacteriology, animal virology, biological sciences, environmental and applied microbiology, medical technology, and molecular biology.
- The four most frequently selected academic training specialties for current postdoctorate trainees are molecular biology, biochemistry, animal virology, and clinical/medical microbiology.
- Approximately 27 percent of all respondents received Federal support for their research; NIAID and NCI together supported 33.6 percent of ASM members.

Recommendations Resulting From Study

The director, Extramural Activities Program (EAP), NIAID, appointed a committee of senior NIH staff experienced in training issues, to consider the ASM report and develop recommendations for the Director, NIAID. During the early meetings of the committee, additional information was identified as desirable for the complete development of the recommendations. Questions were posed that could be answered using the existing computer-stored data from the questionnaires and the process for obtaining the required information developed.

Recent decisions within the NIAID have resulted in a realignment and expansion of responsibilities for training and other aspects of manpower development and led to the creation of the Office of Research Manpower Development (ORMD) within the OD, NIAID. The Chief of ORMD has the responsibility for continuing work on the development of recommendations based on the ASM study. Subsequent to the selection of appropriate courses of action by the Director in consultation with the NIAID Advisory Council, any new approaches or changes will be implemented.

9

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES

Dr. Lester Salans, Acting Director

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Proposed Budget

		Dollars in Thousands FY 81	FY 82	FY 83
NIAMDD 78-2	Evaluation of the Hematology Program of NIAMDD in Relation to Identification of Research Needs	--	--	--
NIAMDD 79-303	Development of Methods for Evaluation of Center Grant Programs	135	--	--
NIAMDD 79-304	Evaluation of the Specialized Centers of Research (SCORs) in Urolithiasis in Relation to Program Goals	--	180	--
NIAMDD 79-305	Identification of Methods for Evaluation of Non-Research Activities of Multipurpose Arthritis Centers	60	--	--
NIAMDD 80-301	Evaluation of the NIAMDD Musculoskeletal Diseases Program	91	140	--
NIAMDD 81-301	Evaluability Assessment of the NIAMDD National Diabetes Information Clearinghouse	50	--	--
NIADDK 82-301	Utilization of Products Disseminated by the National Diabetes Information Clearinghouse	--	50	--
NIADDK 82-302	Evaluation of Postdoctoral Research Training in the Diabetes, Endocrine and Metabolic Diseases Program	--	80	80
	Total FY 82 Set-Aside Fund Request		$450	

Policy Overview

A. Program Structure

The National Institute of Arthritis, Diabetes and Digestive and Kidney Diseases (NIADDK) conducts and supports research and research training in the broad areas of arthritis, musculoskeletal and skin diseases; diabetes, endocrine and metabolic diseases; digestive diseases and nutrition; and kidney, urologic, and blood diseases. This program is supported through research grants, individual and institutional research training awards, applied research and development programs, contracts, and epidemiologic and clinical studies.

Evaluation is an integral part of the Institute's research and research training programs, which are primarily organized in terms of the following four extramural divisions or "clusters."

Arthritis, Musculoskeletal and Skin Diseases Program
Diabetes, Endocrine and Metabolic Diseases Program
Digestive Diseases and Nutrition Program
Kidney, Urologic and Blood Diseases Program

B. Evaluation Strategy

Evaluation studies of NIADDK programs have been conducted periodically throughout the Institute's history to provide a rational and informed basis for managerial decision-making, provide the Congress and the Department with mandated evaluation reports, and respond to public concerns for accountability in government. This approach constitutes a flexible, multi-focus evaluation strategy that will continue to evolve as evaluation needs change and new methodologies are developed.

Evaluation studies have been undertaken to determine the extent of scientific progress toward the objectives of existing programs. From this assessment, a determination is made as to whether the program has been responsive to these perceived needs, and whether a change in activities is necessary. The results of the evaluations also provide management with an effective tool to use in maintaining balance between programs and mechanisms of funding. The evaluation process is closely linked with long-term strategic planning as well as with the annual processes of legislative planning and implementation and budget allocation.

The NIADDK has benefited from evaluations conducted by commissions and advisory boards established by the Congress and funded by the Institute. The national commissions on arthritis, diabetes, and digestive diseases have conducted thorough evaluations of NIADDK program activities while developing comprehensive national plans for combatting these diseases. Recommendations contained in resultant reports[1] have provided a valuable

[1] Arthritis: Out of the Maze Vol. 1: The Arthritis Plan, DHEW Publ No. (NIH) 76-1150, April 1976; Report of the National Commission on Diabetes, DHEW Publ No. (NIH) 76-1018, December 1975; and Report of the National Commission on Digestive Diseases, DHEW Pub. No. (NIH) 79-1978, January 1979.

framework for strategic Institute planning and policy decisions concerning new initiatives.

Another feature of the Institute's evaluation activities is the conduct of formal and informal internal evaluations, well-integrated with NIADDK management functions. Each year the Institute Director meets individually with the Associate Director and staff of each cluster, together with staff of the Institute Office of Program Planning and Evaluation, in order to review ongoing program activities, assess recent accomplishments, and discuss proposed efforts. These meetings precede submission of the NIADDK three-year Research Plan to the NIH Director and provide an important systematic opportunity for retrospective and prospective program evaluation.

The ultimate goal of the Institute's evaluation processes is to provide information that will help the Institute determine how research and administrative activities can be strengthened in order to maximize the efficiency, effectiveness, and responsiveness of NIADDK programs. It should be emphasized, however, that the Institute's ability to effect prompt program changes as a result of evaluation studies is largely a function of resource availability, as well as the degree of managerial control that can reasonably be exercised, given that investigator-initiated research grants are the predominant component of all NIADDK extramural programs. The most direct managerial interventions available to NIADDK are: (1) to issue "Program Announcements" signifying general Institute interest in a particular research field or facets thereof, and "Requests for Applications" indicating the Institute's interest in pursuing specific research directions and in receiving and entertaining grant applications in given research areas; (2) to convene workshops and conferences to stimulate research interest and grant applications in given research areas; and (3) to publish "Requests for Proposals" for research and development contracts, a funding mechanism that represents a relatively small proportion of the Institute's research portfolio. Funding commitments for investigator-initiated research grants average three to four years; therefore, the program changes that can be effected through these interventions are necessarily gradual in nature. Although the Institute may begin to respond immediately to recommendations contained in recently completed evaluation studies, the impact of these actions on program content, emphases, and other programmatic aspects may not be discernible for several years.

C. Completed Evaluations

A recently completed evaluation of Research Needs in Nephrology and Urology (NIAMDD 74-1)[2] resulted in publication of a five-volume report that has already had an impact and is expected to continue to serve as a basis for designing future program activity, as a guide to constructing research budgets, and for informing the general public

[2] Research Needs in Nephrology and Urology, 5 Vol., DHEW Publ. No. (NIH) 78-1481, 1978.

concerning needs for research in this area. This evaluation study was accomplished by a series of specialty committees of experts who reported to a coordinating committee. This coordinating committee reviewed the findings of the specialty committees to avoid overlap and to assure that critical areas were covered. Needs for intensified efforts were recommended in specific areas of basic and clinical research, research resource development, research training, and program coordination.

This broad group of experts concluded that the most promising approach to solving the problems caused by diseases of the kidney and urinary tract consists of broader and more intensive basic research through the support of individual investigator-initiated research grants. Consistent with this recommendation, the Institute has placed primary emphasis on the research project grant mechanism, resulting in a substantial increase in the number of RO1s and a phaseout of the research contracts program which was devoted to development of improved methods of therapy in end-stage renal disease treatment. Further utilizing the recommendations of this study, NIADDK has continued efforts to encourage scientists to submit grant applications in the areas relevant to chronic renal disease, its causes, complications and treatment; to expand the data base of information on incidence and prevalence of kidney and urinary tract diseases; and to collaborate with other agencies concerned with problems of end-stage renal disease. Workshops and conferences have been sponsored to present the state of the art in research in the area of chronic renal failure and in immunosuppressive maintenance therapy in renal transplantations. In addition, symposia have been organized and special presentations made at conferences stressing research needs in this area.

An Evaluation of Research Alternatives to Minimize SSA Medicare Costs for Dialysis Treatments (NIAMDD 75-3) was completed recently. This project was set up to establish and evaluate the most frequent causes of costly hospitalization in a large representative population of stable hemodialysis patients. The objective was to identify factors which interfere with rehabilitation in order to permit a reduction in costs and an improvement in the quality of life of the chronic maintenance dialysis population. As a result of this study, it was recognized that not only did vascular access-related problems constitute the most frequent cause of hospitalization, but that the type of vascular access was directly related to risk of hospitalization. It is hoped that the recent publication of this study in the medical literature will stimulate additional investigator-initiated research in the field of blood access for improved treatment and diminished complications in hemodialysis patients. The Institute feels that any research work established, planned, or conducted in this area should help to advance our knowledge, improve clinical management of patients, and contribute to diminishing the cost of hospitalization and treatment of end-stage renal disease.

A comprehensive study of the needs and priorities of research in skin diseases was commissioned by NIADDK in response to a Senate mandate

(94th Congress, Senate Report No. 94-997, p. 52) (NIAMDD 77-3). The objectives of this study were to provide an increased understanding of the major dermatologic problems that currently beset Americans, and to provide a comprehensive basis for support of research in this area. Eleven major problems in skin biology and skin diseases were examined. The final report included a clarification and definition of the problem, data on the prevalence, the severity, and the effect of dermatologic disease on the quality of life, and an estimate of its overall cost. The present status of prevention, treatment, and cure for the given diseases was reviewed. Detailed analyses of current knowledge and status of research, both basic and clinical, were developed. The final report of this analysis was published as a Supplement to the November 1979 issue of The Journal of Investigative Dermatology, and has been broadly disseminated. Since the publication of this report, the number of applications with high priority scores for research support in the area of skin diseases has increased significantly. The NIADDK is currently drafting program announcements that will invite submission of new project proposals dealing with the various research opportunities outlined in this report. Established as well as new investigators will be encouraged to compete for research and research training support. A joint effort by NIH and the research community will serve to generate a stronger science base and hopefully provide stable and predictable funding for a wide spectrum of basic and applied research efforts in laboratory and clinical settings that will lead to substantial research accomplishments in this area.

Another Senate-mandated study, the Evaluation of Research Needs in Endocrinology and Metabolic Diseases (NIAMDD 77-1), has been completed with the exception of the receipt of the detailed technical reports from the 17 task forces that were established to conduct in-depth evaluations of specific areas in the field of endocrinology and metabolism. The purpose of the project was to evaluate the fields of endocrine and metabolic diseases by highlighting past accomplishments of research in these fields and relating them to improvements in human health and well-being, and summarizing the current state of the art of research in these fields to provide background and documentation for recommendations for future directions and emphasis of research programs. While it is premature to judge the impact of this study on the Institute, positive steps have been taken to implement some of the recommendations. For example, the Institute sponsored a workshop on the use of monoclonal antibodies in endocrine research, an area which both the task force and Institute staff believe may be the source of a major breakthrough in developing new diagnostic techniques for detecting human disease states. It is felt that recommendations of this evaluation study will serve to guide many future research activities of the NIADDK.

D. Ongoing and Previously Approved Evaluations

An Evaluation of the Hematology Program of NIADDK in Relation to Identification of Research Needs (NIAMDD 78-2) is scheduled to be

completed in 1981. This project was initiated to analyze the current state of research in hematology, identify gap areas and the technological advances needed to close them, assess the need for a detailed study of hematology research manpower, and evaluate the extramural hematology program of NIADDK in relation to the identified needs.

A previously approved evaluation, Identification/Development of Methods for Evaluation of NIADDK Center Grant Programs (NIAMDD 79-303), has been revised and resubmitted. This evaluation will be conducted through a research contract that is expected to be awarded in fiscal year 1981. The NIADDK provides grant support for three types of centers: specialized research centers, "core" diabetes-endocrinology research centers, and multipurpose centers for diabetes and arthritis. The PHS Act requires annual evaluation of the arthritis and diabetes centers. The purpose of this evaluation project is to develop suitable methodology for evaluating all the various centers programs of the Institute. The methodology designed and developed by this evaluation will be used by Institute staff and advisors to aid in Center program evaluation and development.

Other evaluation plans previously approved and scheduled for initiation in fiscal year 1981 include the following:

Evaluation of the Specialized Centers of Research (SCORs) in Urolithiasis in Relation to Program Goals (NIAMDD 79-304) will be initiated to compare the effectiveness of Special Centers of Research (SCORs) in urolithiasis (kidney stones) with other support mechanisms for stimulating research in this area. It is anticipated that this evaluation will provide NIADDK managers with needed information about the SCOR as a suitable program mechanism.

A project to identify methods for evaluation of non-research activities of Multipurpose Arthritis Centers (NIAMDD 79-305) is being initiated to identify appropriate methodologies for assessing the effectiveness of education studies and community demonstration activities conducted by the centers.

The goals, performance, and managerial approaches of the Musculoskeletal Diseases Program will be evaluated in order to provide a foundation for improving research efforts (NIAMDD 80-301). This project will also provide an assessment of the health-care impact of selected medical technologies that have been developed with program resources.

An evaluability assessment of the NIADDK National Diabetes Information Clearinghouse will be conducted to review clearinghouse objectives, activities, performance measures, and performance data to determine the conditions necessary for the conduct of a meaningful and useful evaluation of this subprogram (NIAMDD 81-301).

New Proposals

The NIADDK is applying for $50,000 in fiscal year 1982 set-aside funds to conduct an evaluation study on the "Utilization of Products

Disseminated by the National Diabetes Information Clearinghouse" (NIADDK 82-301). This evaluation will entail the development of a questionnaire and its administration to a representative sample of clearinghouse users. Specific questions to be answered include:

- Do clearinghouse recipients use and are they satisfied with the materials they receive?
- Do clearinghouse materials answer a major informational need for diabetes health care providers?
- What do utilization data suggest concerning the discontinuation of existing products or the need for new ones, and their differential distribution?

The survey results should provide a rational basis for managerial decisions concerning clearinghouse operations, specifically on the particular products produced and disseminated, identification of "user needs" that are not being met, and suggestions for the types of new products that should be disseminated to meet these needs. It is also expected that the data obtained will help facilitate Departmental approval of clearinghouse materials. This study is closely related to the evaluation project NIAMDD 81-301, "Evaluability Assessment of the NIAMDD National Diabetes Information Clearinghouse," which is scheduled to begin in fiscal year 1981. The proposed study will complement the evaluability assessment and provide information on a discrete aspect of clearinghouse activities that would not be obtained in an evaluability assessment. The results of both studies will give program and Institute management a more complete understanding of clearinghouse operations and of the possible ways in which they can be improved.

A project to assess the impact of institutional training grants and individual fellowships from NIADDK in the fields of diabetes, endocrine and metabolic diseases on the pool of active biomedical research scientists is being submitted as an evaluation proposal titled "Evaluation of Postdoctoral Research Training in the Diabetes, Endocrine and Metabolic Diseases Program" (NIADDK 82-302). The proposal is for the design and implementation of the necessary conceptual framework, data analysis of relevant files, and survey of a sample of participants to determine the impact of various training policies and mechanisms and identify the possible determinants of the observed outcomes. This proposal is requesting $80,000 of set-aside funds in fiscal year 1982.

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES

Evaluation of Research Needs in Nephrology and Urology

Definition and Description of Program

The Kidney Disease and Urology Program supports extramural research and research training into basic mechanisms underlying biologic processes and diseases in the relevant disciplines of nephrologic and urologic systems and related disorders. The major support mechanism is the investigator-initiated research grant. Both formal and informal coordination of areas of overlapping and complementary interests are maintained with other NIH Institutes, other agencies, outside groups, and scientists in the field. A total of $37 million was associated with this program in FY '80.

Evaluation Study Performed

Design of Study

The objectives of this study were to assess the state of the art of research in nephrology and urology and make recommendations for future research in these areas. This evaluation study was performed by a series of specialty committees, whose work was coordinated and reviewed by a coordinating committee of 13 members representing all aspects of nephrology and urology. Each specialty committee was charged with the responsibility of (1) evaluating the current status of research in its field; (2) designating areas in which greater effort is needed; (3) identifying areas in which research may be particularly feasible and have good prospects of leading to significant benefits for patients; and (4) assessing the human and economic costs of kidney and urinary tract diseases when data are available. Approximately 100 experts, widely representative of all aspects of nephrology and urology, participated in the study.

Recommendations

Results of this study were presented in a 1978 report to the Institute. In its general recommendations, the committee expressed the following views:

- That broader, more intensive basic research is the most promising approach to a solution of the manifold medical, social, and economic problems caused by diseases of the kidney and urinary tract;

- That support of individual investigator-initiated research holds the most promise for significant new and innovative achievements, and that an equivalent expenditure to support a few very large all-inclusive "kidney centers" would not be as cost-productive or beneficial;

- That the need for additional epidemiological studies was identified by several of the specialty committees;

- That attention to the training of an adequate number of investigators in nephrology and urology is essential.

Organization Response

The program has utilized the recommendations of the study over the past two years to indicate to the field where new research endeavors should be encouraged and initiated, for designing future program activity, and as a guide to constructing research budgets.

Implementation

Actual Changes Adopted

As recommended by the study, the Institute has placed primary emphasis on the research project grant mechanism in an effort to generate more interest in this field of research. The research contracts program that was devoted to development of improved methods of therapy in end-stage renal disease treatment has been phased out. Five specialized centers of research (SCORs) in urolithiasis were funded in September 1977. These have facilitated cross-disciplinary work in urolithiasis, a disease that requires coordination of contributions from many disciplines. Efforts have been increased to acquire better data about incidence and prevalence of kidney and urinary tract diseases, and workshops and conferences have been sponsored in areas where potential exists for advancement, such as immunology of renal diseases and the effects of drugs and environmental toxins on the kidney.

Implementation Process

Largely as a result of this evaluation study, NIADDK has integrated its research contract program in kidney diseases with its research grant program. Moreover, consistent with the findings of this study, the Institute is placing primary emphasis on investigator-initiated research grants in the areas of nephrology and urology.

The five SCORs in urolithiasis have shown a considerable degree of cross-disciplinary collaboration and productivity. All of the SCORs have been visited at least once. Their productivity is attested to by the fact that a third of the papers on the program of the Fourth International Urolithiasis Research Symposium held in June 1980 were presented by investigators supported by SCORs. An evaluation of the SCORs, both for their success in encouraging research in the area of urolithiasis and as a mechanism for stimulating research in this area, is scheduled to begin in FY '81.

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES

An Evaluation of Research Alternatives To Minimize SSA Medicare Costs for Dialysis Treatments

Definition and Description of Program

The Chronic Renal Disease Program supports investigator-initiated research into fundamental mechanisms and treatment of complications of chronic renal failure. These fall into three categories: pathophysiology of chronic renal failure, renal transplantation, and maintenance therapies. The Chronic Renal Disease Program is under the Kidney Diseases and Urology Program, which had actual expenditures of $37 million for FY '80.

Evaluation Study Performed

Design of Study

This evaluation study was conducted by in-house staff. Its objective was to evaluate the most frequent causes of hospitalization in a large representative population of stable hemodialysis patients. The aim was to identify factors that interfere with rehabilitation in order to reduce costs and improve the quality of life of the chronic maintenance dialysis population.

Data were collected on the incidence of complications of dialysis patients, the relationship of the complications to the mode of therapy, and the medical history of the individual, as well as other characteristics of the patient. Additional data were gathered on the cost of treatment of various medical complications experienced by dialysis patients. These data were obtained during calendar year 1976 from the hospital records of five major providers of hospitalization for chronic renal failure patients. The data were then analyzed, using the NIH computer facilities. In addition, suggestions were provided by experienced investigators and physicians in the field for research approaches directed toward minimizing dialysis complications, improving self-dialysis methodology, or reasonable alternative therapies for the dialysis patient.

Results of Data Analyses

The study population comprised 1,049 patients from five hemodialysis centers widely separated geographically, who were studied during a one-year period;

509 of the patients were females and 540 were males. Mean age was 51 years and mean length of chronic hemodialysis therapy was 2.3 years; 51 percent of the population was hospitalized at least once during the year. Vascular access-related problems were the most frequent cause of initial hospitalization during this period, accounting for 26 percent of all hospitalizations in the group. Most procedures were access revision; however, thrombosis and infection were also listed as causes of hospitalization, followed by infection, cardiovascular-related problems, and hypertension. Patients with diabetic nephropathy as the underlying process leading to chronic renal failure showed a higher average of hospitalizations than those with polycystic kidney disease, pyelonephritis, glomerulopathies, or other types of kidney disease.

Problems related to vascular access had been recognized previously; however, actual quantifications of their frequency were unknown. As a result of this study, it was recognized not only that vascular access-related problems constituted the most frequent cause of hospitalization, but that the type of vascular access was directly related to risk of hospitalization. The relative risk of hospitalization for an access-related cause for patients with bovine fistulas or shunts was five times greater than for patients with Cimino AV fistulas. Also, patients with shunts or bovine fistulas have relative odds of at least one hospitalization for any other cause, almost double those of patients with Cimino AV fistulas.

Recommendations Resulting From Study

The results of this study showed a clear need for additional research specifically focused on improved vascular access methods and devices to improve clinical management and decrease incidence of costly hospitalizations in maintenance dialysis treatment.

Organization Response to Recommendations

The Institute believes that any meritorious research planned or conducted in the area of vascular access should help advance our knowledge, improve patients' clinical management, and contribute to diminishing the cost of hospitalization and treatment of end-stage renal disease in general.

Implementation

Actual Changes Adopted

The Institute has shifted its emphasis toward the investigator-initiated research project grant. In doing so, it has gradually phased out the contract program in this area. The declining use of the contract mechanism has resulted in a drop in support from 53 contracts in FY '78 to 16 in FY '80.

Implementation Process

The Institute is now placing primary emphasis on investigator-initiated

research grant support. A program announcement indicating broad interest in research into causes, complications, and treatment of chronic renal failure was issued in September 1978. A revision will be issued in 1981. The results of this evaluation study were published in the Journal of Clinical Nephrology in February 1981. It is hoped that this will stimulate additional investigator-initiated research in the field of blood access for improved treatment and diminished complications in hemodialysis patients.

A chronic renal disease conference emphasizing the state of the art of research into the pathophysiology of uremia and one in transplantation were sponsored in January 1980. Another conference to review current research and hold panel discussions of future directions of research in several fields was held March 5 and 6, 1981. The topics discussed at this conference were cystic diseases of the kidney, pediatric end-stage renal disease, glomerulonephritis, and treatment modalities.

Effects of Programmatic Changes

The Artificial Kidney Chronic Uremia Program, whose objective it was to develop technology to reduce the cost of dialysis, was phased out as the result of another study. It was felt that the mechanism would not be as cost-productive or beneficial as the support of individual investigator-initiated research. The Institute is currently placing primary emphasis on the research grant mechanism, with a phasing out of the contract program in this area.

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES

Evaluation of Research Needs in Endocrinology and Metabolic Diseases

Definition and Description of Program

The Endocrinology Program and the Metabolic Diseases Research Program are organizationally a part of the Diabetes, Endocrine, and Metabolic Diseases Cluster of the NIADDK. The Endocrinology Program supports basic and clinical research on the endocrine system. The Metabolic Diseases Research Program supports basic research into the mechanism of cellular functions and metabolism as they pertain to understanding the etiology, pathogenesis, prevention, diagnosis, and treatment of metabolic disorders. These programs had a combined budget of $87.5 million for FY '80.

Evaluation Study Performed

Design of Study

In its report on FY '78 appropriations for the Departments of Labor and Health, Education, and Welfare, the Senate Appropriations Committee directed the Director, NIH, to "undertake a study of endocrine research, which now exists in most Institutes and several agencies throughout the Federal Government, to pull together into an overview all of the past accomplishments, the present state of research in the field, the directions offering best opportunities for research advance, and problems preventing the most rapid flow of information among agencies and institutes."

At the time of this request, NIADDK was conducting a study entitled "An Evaluation of Research Needs in Endocrinology and Metabolic Diseases." To avoid a duplication of effort, this study was modified to fulfill the Senate request.

An advisory committee of recognized experts in subspecialties of endocrinology and metabolic diseases was recruited to work with the chairman on defining the goals of the study. Seventeen topic areas were specified and a task force established for each. The task forces met on an individual basis to conduct detailed evaluations of the specific areas. Announcements in several scientific publications solicited the participation of interested members of the scientific community through written contributions. In

addition, all NIH Institutes concerned with endocrine research were invited and encouraged to participate as actively as possible in the work of the task forces. A final report incorporating major findings of the study was submitted to the Senate in February 1980. The individual reports of the 17 task forces are now being completed.

Results of Data Analyses

The evaluation findings showed that Federally supported research in endocrine and metabolic diseases has contributed substantially to improvements in human health and well-being. These contributions have included more accurate, efficient, and economic diagnosis of endocrine diseases; improved treatment of disorders of bone and mineral metabolism through discovery and synthesis of the hormone calcitonin and of the active form of vitamin D, development of natural and synthetic agents effective in diagnosing and treating infertility in men and women; improvements in medical practice through the discovery and use of radioimmunoassay, a technique for measuring hormones and other compounds with great specificity, sensitivity, and economy; and the use of hormones as therapeutic agents.

Areas for future research opportunities in endocrine and metabolic diseases were identified:

- Mechanisms of hormone action
- Hormone interactions
- Biogenesis and fate of hormones
- Biology of target organs
- Disease mechanisms
- Hormones and pharmacotherapy

Recommendations Resulting From Study

The Advisory Committee and task forces considered the problem of manpower shortage to be the utmost concern. They made several recommendations to alleviate difficulties in developing and maintaining a pool of well-trained scientists. These recommendations include eliminating the payback provision and increasing the inadequate stipends.

Other recommendations include shortening the review process for both individual and institutional NRSAs through mechanisms that would maintain the quality of review; increasing emphasis on training grants for basic science departments and strengthening interdisciplinary training in the basic sciences, with specific provisions for M.D. trainees; and seeking and implementing mechanisms to increase the coordination of funding for research training and funding for research itself.

The report recommended that NIADDK expand the scope of the National Pituitary Agency to include production and distribution of additional hormones, antibodies, and other biologic products for endocrine research. The Advisory Committee also felt that consideration should be given to establishment of special institutional equipment grants to meet such needs where they can be demonstrated to exist.

Organization Response to Recommendations

Other Institutes at NIH, as well as NIADDK, are utilizing this report as a guide to program planning, budgeting, and collaborative efforts with other government agencies and the scientific community.

Implementation

Implementation Process

The final report submitted to the Senate was broadly distributed in hopes of strengthening existing communication and developing additional collaborative efforts between NIADDK, other NIH Institutes, the scientific community, and other government agencies whose interests are in these areas. The 17 task force reports will be equally distributed as soon as they are printed.

The NIADDK is taking positive steps in response to the recommendations of the study. It sponsored a workshop on the use of monoclonal antibodies in endocrine research. This is an area which both the task forces and Institute staff believe may be the source of a major breakthrough in developing new diagnostic techniques for human disease states.

In response to recommendations concerning support of the National Pituitary Agency (NPA), the Institute convened a small group of experts in June 1980 and again in August to advise NIADDK management concerning future alternative directions for this program. The recommendations will aid in formulating a new workscope for the NPA contract.

NIADDK and NINCDS jointly sponsored a workshop relating to brain peptides and will soon publish a joint program announcement concerning research opportunities in this area. In addition, NIADDK is planning a workshop in collaboration with NCI to discuss the role of prohormones and other products of the endocrine system as tumor markers. It is hoped that this will result in a joint program announcement. Several other workshops are currently in the planning stages.

The program anticipates an increase in training slots funded through both institutional and individual NRSA awards.

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES

Analysis of Needs and Priorities for Dermatologic Research

Definition and Description of Program

The Skin Diseases Program supports clinical and laboratory research on both normal and diseased skin. Research training is encouraged and supported through National Research Service Awards, both individual fellowships and institutional awards; Clinical Investigator Awards; and Research Career Development Awards. In FY '80 this program had expenditures of $9.5 million.

Evaluation Study Performed

Design of Study

In its report on the Labor/DHEW appropriations bill for FY '77, the Senate Appropriations Committee recognized the "tremendous socioeconomic costs associated with dermatologic diseases" and directed NIADDK to conduct "an analysis of the needs and priorities for dermatologic research." Utilizing evaluation set-aside funds, a contract was awarded to a group of distinguished dermatologists to provide the Institute with a comprehensive basis for support of research and an individual understanding of the major dermatologic problems that beset Americans. The Coordinating Committee selected 11 major problem areas in skin biology and skin diseases, basing its selection on research activities and opportunities, societal needs, and the clinical problems faced by dermatologists. The contributors were instructed to define the problem; to report on the prevalence, severity, and the effect of dermatologic diseases on the quality of life; and to estimate their costs. In addition, the group reviewed the present status of prevention, treatment, and cure for given diseases and developed a critical statement of current knowledge and status of research, both basic and clinical, for each.

Results of Data Analyses

Reports of the analysis were published as a supplement to the November 1979 issue of The Journal of Investigative Dermatology. In addition, the report contains a summary statement emphasizing current needs in manpower, technology, and collaborative effort. The report as a whole provides an in-depth analysis of current problems, existing knowledge, treatment methods, and research needs and opportunities.

Recommendations Resulting From Study

- Increased attention should be given to research on psoriasis, atopic dermatitis, collagen and connective tissue diseases, blistering diseases, and acne.

- Special priority should be given to research on birth defects and congenital disorders.

- Primary focus of programmatic effort within the Institute should be on manpower development (through training, career development, research support mechanisms, interdisciplinary efforts) and additional research funding (through broader recognition of needs).

Implementation

Actual Changes Adopted

NIADDK is drafting program announcements that will invite submission of new project proposals dealing with the research opportunities outlined in the report. Both new and established investigators will be encouraged to apply.

Implementation Process

In order to develop a stronger interest in dermatology-related research and to reach the broadest group of qualified investigators, the Institute distributed the report to Directors of NIH Institutes, the Food and Drug Administration, the National Institute of Occupational Safety and Health, and the National Center for Health Care Technology.

A newly created interagency dermatology working group met for the first time in FY '80. It includes representatives from several NIH Institutes, the National Center for Health Care Technology, the Food and Drug Administration, and the Environmental Protection Agency. Its first task is to assist the Dermatology Foundation in publishing a pamphlet listing research training opportunities in dermatology throughout the country. The formation of this working group reflects the increasing support of dermatology and related research by other NIH Institutes.

The Skin Diseases Program conducted a seminar on grantsmanship at the May 1980 meeting of the Society for Investigative Dermatology to provide young investigators with a better understanding of the grant review process.

NIADDK has sponsored and organized workshops and seminars on epidermolysis bullosa, the biochemistry of keratinization, and the effect of dialysis on psoriasis. The Skin Diseases Program published A Look at Management of Psoriasis, which was directed toward nondermatologist physicians who might encounter psoriasis in their practice.

Effects of Programmatic Changes

In the short time since publication of the report, there has been an increased number of applications with high priority scores for research support in the area of skin diseases, and the number of new applications has doubled. Many of the research opportunities outlined in the report have led to progress in several areas and a demand for state-of-the-art workshops in others. Support for dermatology-related research by NIADDK and other Institutes continues to increase.

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES

Evaluation of the State of the Art and Directions for Future Research Efforts in Cystic Fibrosis

Definition and Description of Program

Research on cystic fibrosis (CF) and related topics represents a special focus of the Metabolic Diseases Program, since CF is the most common lethal inborn error of metabolism among Caucasian children. Although recent years have seen marked reductions in both mortality and morbidity, the basic defect response for the disease remains unknown, and only 2 of every 100 CF patients live to the age of 30. In FY '80, $3.4 million was spent to support research on cystic fibrosis.

Evaluation Study Performed

Design of Study

This study was undertaken in FY '78 in response to a Congressional directive and concerns of the health care and lay communities that vigorous attempts be made to identify research opportunities and needs in the area.

The study was conducted by the Cystic Fibrosis Foundation and jointly funded with program funds of NIADDK and and NHLBI. Over 150 scientists, physicians, allied health professionals, health care administrators, public representatives, Government officials, and CF patients and their families participated. They were organized into working groups on (1) clinical sciences, (2) basic sciences, (3) education and manpower, (4) support services and therapeutic interventions, and (5) consumers and delivery systems. Each group was responsible for delineating current and relevant issues in its area of expertise, describing the state of the art with respect to these issues, and developing a series of recommendations.

Recommendations

Major recommendations were developed in the following areas: clinical and basic research, research resource development, research training, and program coordination and implementation.

In the area of clinical and basic research, a research enhancement program was recommended to provide additional support in the following major program areas:

- Respiratory disease in CF
- Metabolic defects in CF and the search for CF markers
- The secretory process in CF
- Digestive and nutritional problems in CF
- Standardization of tests used in diagnosing and evaluating CF

A research resources program was recommended to provide support to enhance the resources needed to support investigative efforts in basic and clinical research related to CF, provide specialized resources to support the conduct of research, provide resources for the training and education of scientific personnel needed to carry out research on CF, and to provide the environment to expedite the rapid transfer of new technology and knowledge.

It was recommended that additional support be provided to train scientific personnel for conducting basic and clinical research in the field.

It was recommended that the NIH Cystic Fibrosis Coordinating Committee should be continued and augmented by inputs from other Federal and private agencies that sponsor cystic fibrosis research in order to enhance and communicate these efforts.

Organization Response

The Institute has been responsive to the recommendations of the report in encouraging and supporting additional research in the areas recommended.

Implementation

Actual Changes Adopted

NIADDK has been designated as the lead Institute in matters regarding cystic fibrosis. In response to the recommendations outlined in the report, NIADDK has published and widely distributed a program announcement in which five Institutes participated (NIADDK, NIAID, NICHD, NHLBI, and NIGMS). This announcement requested research project applications in the wide range of areas represented in the report. Applications for National Research Service Awards (NRSAs) are actively sought, and several have been funded. A Special Emphasis Research Career Award in cystic fibrosis is planned for FY '83. This award will focus on drawing clinically trained individuals into research on cystic fibrosis with the objective of developing research skills in several disciplines relevant to cystic fibrosis.

Considerable progress has been made in the past two years in obtaining various purified mucins for laboratory research, and supplying these to investigators as available. The establishment of a tissue bank as a contract effort is planned for FY '83.

Implementation Process

NIADDK and four other Institutes (NIAID, NHLBI, NICHD, and NIGMS) involved in CF research developed an announcement calling for research applications in CF. Since the report was issued, there has been a substantial increase in the number of CF-related grant applications. A series of brochures on CF were published and widely distributed to the research community. Also, the Institute has funded the production of a half-hour film entitled "Living with Cystic Fibrosis." It is intended as an introduction to the disease for health professionals and the general public and is being distributed by the Cystic Fibrosis Foundation.

There has been continuing coordination/collaboration with other Institutes, agencies, and countries. Support has been provided for an international meeting on cystic fibrosis. An RFP will be let for a contract to provide a cyctic fibrosis tissue and materials repository; in addition, RFAs will go out for development of Special Emphasis Research Career Awards (SERCA) in Cystic Fibrosis.

Effects of Programmatic Changes

The cystic fibrosis evaluation study and resultant initiatives by several Institutes at NIH have undoubtedly contributed to the stimulation of new research ideas in the field and have affected NIH and Institute program content with respect to research in this disease. Applications for research grants in cystic fibrosis assigned to the NIADDK have increased substantially since FY '77. New projects funded by the Institute have tripled since FY '77.

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NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Dr. Betty Pickett, Acting Director

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Proposed Budget

		Dollars in Thousands FY 81	FY 82	FY 83
NICHD 80-305/306	Development of Objectives and Performance Indicators for NICHD Programs of Research for Mothers and Children and Population Research	7	5	--
NICHD 81-302	Stage 2 Evaluation of NICHD Sudden Infant Death Syndrome Research Program	--	20	--
NICHD 81-304	Stage 1 Evaluation of NICHD Intramural Research Program	--	70	--
NICHD 82-301	Evaluation of NICHD Research Resources Program	--	65	--
NICHD 82-302	Stage 2 Evaluation of NICHD Child and Adolescent Development Research Program	--	20	--
NICHD 82-303	Stage 2 Evaluation of NICHD Population Dynamics Research Program	--	20	--
	Total FY 82 Set-Aside Fund Request		$200	

FY 1982 Evaluation Strategy Statement

1. Research Strategy

The mission of the National Institute of Child Health and Human Development (NICHD) is to conduct and support research on the reproductive, developmental, and behavioral processes that determine the health of children, adults, families, and populations. In pursuit of this mission, the NICHD administers a multidisciplinary program of research, research training, and public information nationally, internationally, and within its own facilities, on population and on maternal, child, and family health.

The Institute's programs are based on the concepts that adult health and well-being are determined in part by episodes early in life, that human development is continuous throughout life, and that reproductive processes and the management of fertility are of major concern not only to the individual but to the whole of society. The Institute supports research in the reproductive sciences to develop knowledge that will enable men and women to regulate their fertility with methods that are safe, effective, and acceptable to various population groups, and to overcome problems of infertility. In the population, social, and behavioral sciences, the purpose of Institute-sponsored research is to understand the causes and consequences of population change. Research for mothers, children, and families is designed to advance knowledge of fetal development, pregnancy, and birth; to identify the prerequisites of optimal growth through infancy, childhood, and adolescence; and to contribute to the prevention and treatment of mental retardation.

2. Evaluation Strategy

Achievement of the mission and goals of the NICHD is dependent upon effective evaluation of virtually every facet of the Institute's activities. Throughout its 18-year history, the Institute's leadership has sought to develop and refine a system for evaluation and review of its programs and administrative activities. These efforts, which have contributed substantially to the Institute's past effectiveness, will be continued, expanded, and strengthened, wherever possible, in the future.

In recent years, the NICHD has undertaken to formalize and intensify its evaluation activities. The Institute's numerous ongoing in-house evaluation efforts range from review of intramural and extramural research programs, operations, and personnel, to management analyses undertaken by the Office of the NICHD Director. The Institute is committed to the process of identification and development of goals and objectives for its total and component efforts, and to regular assessment of its progress in achieving those goals.

Typical of the Institute's evaluation activities is the program review conducted by the National Advisory Child Health and Human Development

Council at each of its meetings. All programs of the NICHD are of each program makes a comprehensive presentation at its Council review session, and provides the Council members with an extensive written report of its objectives and activities.

In 1976 the Institute divided its research activities into the following 10 program areas: pregnancy, birth, and the infant; fertility and infertility; congenital defects; sudden infant death syndrome; child and adolescent development; nutrition; mental retardation; contraceptive development; contraceptive evaluation; and population dynamics. The NICHD Evaluation Plan for FY 1982 reflects the Institute's continued commitment to these 10 program areas.

In October of 1981 the NICHD anticipates the successful completion of its current Stage 1 evaluation effort (combined NICHD 80-305 and 306) for all of its 10 program areas. As the result of this evaluation (Development of Objectives and Performance Indicators for NICHD Programs of Research for Mothers and Children and Population Research), research areas that can benefit from in-depth analyses have emerged. The current activity has raised important questions regarding program relevance to the Institute's mission and to societal health problems, and directions for future programs. Utilizing the results of this Stage 1 assessment, the Institute plans as its major evaluation objective in FY 1982 to begin a four-year cycle of Stage 2, and then full-scale Stage 3, evaluations of its research programs, intramural research program, and its management and administrative activities.

The current Stage 1 and proposed Stage 2 and 3 efforts are, and will continue to be, responsive to the identified information needs of the Congress, Department, PHS, NIH, and the NICHD itself. The results of these activities are of critical importance to the effective management of the Institute and its programs. In particular, the evaluation study products will be fully utilized in the planning, legislative, budget, and program management functions of the NICHD.

All NICHD evaluation projects are undertaken to obtain information regarding the performance of its various programs and activities. This information is sought to enable the Institute's program managers and policy-makers to make sound, informed decisions on the management of these activities. This requires that the products of evaluation studies be fully utilized and integrated into the management of the Institute's programs and activities. It is the responsibility of the NICHD Office of Planning and Evaluation and the NICHD Director to ensure that all evaluation data are utilized by the Institute's managers and policy-makers. The current evaluation study will provide valuable information to the Institute's leadership to effectively reassess and modify its performance. The projects recommended from this study are designed to yield data which will be helpful to the Institute in its efforts to effectively and efficiently assess its performance.

With the completion of the Stage 1 evaluation of the Institute's

extramural research programs (combined NICHD 80-305 and 306) delayed by seven months, the schedule of performance evaluations for NICHD extramural programs has been pushed back accordingly. Thus, the Stage 2 study of the Sudden Infant Death Syndrome Research Program (NICHD 81-302) was delayed until FY 1982. Also, the preliminary products of the Stage 1 study have led the Institute to rearrange the scheduled order of its program performance evaluations. Specifically, the Stage 2 projects for the Contraceptive Development Research Program (NICHD 81-301) and Congenital Defects Research Program (NICHD 81-303) will be delayed until FY 1983. In their place, Stage 2 evaluations will be conducted on the NICHD Child & Adolescent Development Research Program (NICHD 82-301), and the Population Dynamics Research Program (NICHD 82-302).

Similarly, with the Institute's evaluation resources focused on the large Stage 1 project, the decision was made to delay until FY 1982 the Stage 1 study of the Intramural Research Program (NICHD 81-304) and the evaluation of NICHD Research Resources Program (NICHD 81-306).

The Institute has decided to delay indefinitely its evaluation of the NICHD Career Development Award Program (NICHD 81-305), and its project for the development of an evaluation component for the NICHD Clinical Investigator Award Program (NICHD 81-307).

Major Projects Underway or Recently Completed

Development of Objectives & Performance Indicators for NICHD Programs of Research for Mothers & Children and Population Research (NICHD 80-305/306) - This project, which will develop program objectives and performance indicators for the Institute's 10 extramural research programs, is now scheduled for completion in October 1981. The products of this project will provide the foundation for the scheduled full-scale program performance evaluations of each of the NICHD extramural programs.

The project is the responsibility of a Steering Committee composed of the Institute's senior program leaders and policy-makers--except for the NICHD Director, and several outside expert consultants. For each of the 10 research programs the Steering Committee established a Study Group composed of an outside expert (Key Consultant), health science administrator(s), and intramural staff scientist(s). The Study Groups began their work in February 1980, when they were charged by the Steering Committee to prepare a report on their respective program which answers the four following questions: (1) What is the state of the science? (2) Where are the research gaps and opportunities? (3) What research areas should be pursued in the future? and (4) What resources are necessary?

Upon completion of the Study Group reports by July 1980, each Key Consultant participated in a scientific review of his or her report. These reviews were conducted by the Institute's standing research committees and by groups of ad hoc reviewers. The Steering Committee also reviewed each report to determine that the Study Group had met its charge and for policy considerations. Subsequent to these reviews, Study Groups revised their reports in accordance with changes suggested in the reviews. The revised and edited versions of seven of the reports have received final review and approval by the Steering Committee and the remaining three reports should also obtain final approval within the next several weeks.

For the past several months the Steering Committee has been heavily involved in the development of specific program objectives and performance indicators for each of the programs. The process by which this is being done is as follows: The recommendations for future research as presented by each Study Group report are being examined by a Task Force of the Steering Committee to determine their relevance to the Institute's mission, their relative importance, and whether or not sufficient argument is presented in the Study Group reports for their acceptance. The results of the Task Force deliberations are then arrayed against the existing program of research to identify overlap and redundancies. The results of this process are being presented to the Steering Committee in the form of decision memoranda to assist the Steering Committee and staff in arriving at agreed-upon program objectives and performance indicators for each of the ten programs.

It is anticipated that the final report of this project will be presented to the Institute's National Advisory Council in October 1981.

New Projects Proposed

1. Stage 2 Evaluation of NICHD Child & Adolescent Development Research Program (NICHD 82-301) - Using the program objectives and performance indicators developed in the evaluability assessment of this program (part of combined NICHD 80-305 and 306) to be completed in October of 1981, a full-scale Stage 2 evaluation of this program will be undertaken. The study will carefully examine the program objectives and performance indicators developed by the current project to ensure that they are in measurable terms. The project will then develop an overall study design and the protocols for the collection and analysis of the necessary data.

2. Stage 2 Evaluation of NICHD Population Dynamics Research Program (NICHD 82-302) - This project will be designed and performed as described in No. 1 above.

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Evaluation of the Maternal and Child Health Research and Training Program

Definition and Description of Program

For the purposes of this study, the maternal and child health research and training program was defined as the research and training activities of the NICHD, other NIH Institutes, and other health agencies of DHEW, in the maternal and child health research fields of population, reproduction, pregnancy and uterine physiology, morphogenesis, fetus and newborn, metabolism, growth and development, and nutrition and development. Specifically, "maternal" health was defined as "that aspect of adult female health that is directly relevant to pregnancy and to the health of the offspring." While the study analyzed data on this program for the period FY '71 through FY '75, the in-depth analysis focused on FY '73, when the total expenditures for the program were estimated to be in excess of $30 million.

Evaluation Study Performed

The study, conducted by the National Academy of Sciences' Committee on Maternal and Child Health Research, sought to assess the state of the science to identify research gaps, needs, and opportunities in developmental biology, pregnancy, the perinatal period, and childhood, with respect to the biomedical and psychosocial aspects of human development. In addition, the study sought to define the manpower needs in maternal and child health research, and to evaluate the research development and funding mechanisms used in this field.

The study identified six significant accomplishments and six correctable deficiencies, and also made eight broad recommendations. For the most part, these recommendations related to expanding specific areas of research and training to fill gaps or capitalize on opportunities.

This study was undertaken at the request of Dr. Norman Kretchmer, the NICHD Director, shortly after he assumed that position. He and the senior NICHD staff found the process of implementing the study as well as its final product to be very informative and beneficial. It was particularly helpful in planning future research and training directions in this field. To a large extent, this study provided the foundation and framework for the direction and focus of Dr. Kretchmer's leadership of this field while at NICHD.

Implementation

The impact of this study pervades the development and management of this field of research at NICHD and, to a somewhat lesser extent, at other NIH Institutes and PHS agencies. Implementation within the NICHD involved virtually all of the Institute's activities in this field. Numerous efforts were undertaken to either specifically implement the study's recommendations or to follow the general guidance of the study report. These efforts ranged from the issuance of program announcements and requests for contract proposals to expand research into new areas, to the development of a new funding mechanism to establish specialized centers of research excellence in areas of opportunity and need.

Effects of Programmatic Changes

It is not difficult to find at least preliminary evidence to suggest that changes in direction and management made in this program as a result of this study have been productive and beneficial. New areas and approaches to research that the study identified are being pursued and are yielding valuable new knowledge. Likewise, the study led to the use of new funding mechanisms and provided a conceptual framework, which became the basis for a significant reorganization of much of the NICHD extramural research program.

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Evaluation of the NICHD Mental Retardation and Population Research Centers Programs

Definition and Description of Programs

Begun in 1965 and 1968 respectively, the NICHD Mental Retardation and Population Research Centers programs have grown to be major investments of the Institute. Both of these programs were designed to foster the development of multidisciplinary centers of research excellence in their respective fields. This study focused on FY '77, at which time there were 12 Mental Retardation Research Centers, which received a total of $6.2 million in core support from NICHD, and 22 Population Research Centers, with a total NICHD core support of $3.4 million.

Evaluation Study Performed

Design of Study

The study was conducted by a special task force of five nongovernment expert consultants who are knowledgeable about these programs and the Institute's activities. The study involved collection and analysis of data from a variety of sources, including (1) the use of a special survey instrument to obtain data from each of the centers on numbers of investigators, their discipline, publication output, and area of research specialty; (2) informal visits to a limited number of centers; (3) special studies of staff development and multidisciplinary activities at three selected centers; (4) a peer analysis of the quality and productivity of research of a sample of Mental Retardation (MR) Centers investigators; and (5) in-house NIH records. The data were more complete and more fully analyzed with respect to MR Centers, but portions of the methodology proved applicable to the Population Centers as well.

Results of Data Analysis

From the data it was possible to derive both a composite picture at the national level for MR Centers and Population Centers and an individual picture for each center with respect to (1) general character of the scientific staff; (2) research interests and actual research output during the period 1974-76; and (3) degree and nature of multidisciplinary effort. For the MR Centers, it was possible to examine (1) quality of scientific personnel as assessed by peer review and compared with NIH application success and rating; and (2) additions to the pool of researchers working in

the MR field. Also, for a limited set of case studies of MR Centers, organizational arrangements and their contributions to center success were studied.

Recommendations Resulting From Study

The study report made 27 recommendations: 6 related to the status of the programs and individual centers; 7 to evaluation of these programs; 3 to the procedures used by the programs; 6 to the multidisciplinary efforts of the program; and 5 to the NICHD core support of the programs.

Organization Response to Recommendations

Because some portions of the study methodology and some of the recommendations were controversial, the NICHD leadership responded to the recommendations by launching a thorough review of the evaluation study and its recommendations. This process began with a project review and implementation conference held in February 1979--the month following the release of the study report--and attended by appropriate NICHD, NIH, and DHEW staff, center representatives, and the study task force. Before reaching conclusions in its evaluation of the recommendations and their implementation, NICHD staff further discussed them at two center site visits, two National Advisory Council meetings, two research review committee meetings, with staff members of other NIH institutes and PHS agencies, and at numerous working meetings of NICHD staff.

Implementation

The extensive evaluation of the study recommendations concluded with the development of a set of specific implementation recommendations. These implementation recommendations consistently reflected the general concerns and thrust of the study, while somewhat modifying or, in some cases, rejecting the study recommendations. The implementation recommendations were reviewed by the National Advisory Council and approved by the NICHD Director. Their implementation has resulted in a complete revision of the Institute's guidelines and procedures for the review of all center grant applications. A regular, more formal system of evaluation of the operation and performance of centers has been incorporated into the centers grant reporting and review process as well.

Effects of Programmatic Changes

In the short period since their formal implementation in October 1980, the revisions and modifications in the operation of these programs have significantly strengthened them and made them more efficient. In addition, the breadth of performance data collected by the study has greatly aided program managers and the Institute leadership in making informed decisions about the future of these programs and the individual centers as well.

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Evaluation of the NICHD Research Contract Program

Definition and Description of Program

Use of the contract mechanism to fund research has grown to be a major portion of the total NICHD research effort. Over its 18-year history, the NICHD research contracting program has expanded from an annual expenditure of $118,000--3.7 percent of the overall NICHD research budget--to a total of $27.5 million for FY '80--13.2 percent of the total NICHD obligations for that year.

Evaluation Study Performed

Design of Study

This modest study was performed by a distinguished panel of eight nongovernment expert consultants knowledgeable about research and the NICHD's programs. The panel was charged to review the basic concept of research contracting, the NICHD approach to the use of research contracts, its policies and procedures for the program, and to make recommendations on the efficient and effective future use of the mechanism by the Institute.

The panel collected background and current data on research contracts, especially the NICHD experience with them. These data were obtained from a variety of descriptive and fiscal program records and a series of interviews with a number of NICHD program managers and senior staff.

Recommendations Resulting From Study

Analysis of the data led the panel to conclude that the NICHD research contracts program was sound, but could benefit from some modification to enhance current management. The study recommended several means of strengthening the program, including (1) the use of guidelines to assist the Institute management in deciding whether the contract mechanism is more appropriate than the grant mechanism for a particular research project; (2) the establishment of a requirement that staff planning contracts be more definitive about the anticipated length of the contract; and (3) the development of a more systematic method of preparing an annual NICHD research contracts plan to improve the overall planning and decision-making process.

The recommendations of the study panel were reviewed and approved by the NICHD staff and Director.

Implementation

Implementation of the recommendations was a joint effort of the NICHD Executive Officer, who had served as the project officer for the study; the office of the NICHD Associate Director for Scientific Review; and the NICHD Office of Grants and Contracts. The implementation required revisions of the policies and procedures of the program, and these were reflected in a revision of the NICHD contracts manual.

Effects of Programmatic Changes

Policies and guidelines were developed and implemented which strengthened the process of developing the Institute's annual research contracts plan. These have resulted in improved planning and decision-making by the research contracts program staff and the Institute's senior leadership. The new annual planning policies and guidelines now require staff when planning contracts to be definitive about the anticipated length of the contract. This is expected to improve contract productivity and reduce costs. Guidance has been developed and implemented which will assist in the decision-making process of when to use the contract mechanisms. This, also, is anticipated to be effective in strengthening the research contracts program, as well as the overall research activities of the Institute. In addition, the NICHD Director, who initiated the study, found the review to be informative and beneficial to his leadership of this program.

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NATIONAL INSTITUTE OF DENTAL RESEARCH

Dr. David B. Scott, Director

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Proposed Budget

		Dollars in Thousands FY 81	FY 82	FY 83
NIDR 77-8	Evaluation of the Craniofacial Anomalies Research Activities	10	--	--
NIDR 82-301	Assessment of Selected Objectives Associated With Dental Research Institutes	--	50	50
NIDR 82-302	Evaluation of the Restorative Materials Research Activities	--	250	50
NIDR 83-301	Evaluation of the Soft Tissue Stomatology and Nutrition Research Activities	--	--	275
	Total Set-Aside Fund Request		$300	

Policy Overview

The NIDR mission is "to conduct, assist, and foster researches, investigations, experiments, and studies related to the cause, prevention, and methods of diagnosis and treatment of dental diseases and conditions." To accomplish this goal, the Institute provides grant and contract support to members of the scientific community for the development and conduct of research and for training research manpower. The Institute engages in its own program of intramural research primarily focused on basic science issues underlying problems related to oral diseases and conditions as well as clinical dental research.

The following six categorical program areas provide the focus for NIDR's activities:

- Periodontal Diseases
- Caries
- Craniofacial Anomalies
- Restorative Materials
- Soft Tissue Stomatology and Nutrition
- Pain Control and Behavioral Studies

All areas except that which relates to caries employ only the grant and contract mechanisms to support extramural research and training. The National Caries Program is a unique entity in that it is a targeted effort which can employ grants and contracts as well as direct research operations to develop means to prevent tooth decay. Studies which are conducted by staff of the Intramural Research program can be classified to a large extent by these six major areas, although much of that work cuts across two or more areas of categorical interest.

The NIDR committed itself in the fall of 1974 to undertake a long-range evaluation plan to provide for comprehensive assessments of its six major categorical research programs, using set-aside funds allocated to the Institute each year. The annual allotment, generally less than $300,000, provides for the support of one comprehensive program assessment annually. Limited manpower resources, however, have been determinant in implementing one assessment approximately every other year. The Evaluation of the NIDR Periodontal Research Activity was completed in 1976 and the report resulting from the Evaluation of the National Caries Program was issued in February 1980. The Evaluation of the Craniofacial Anomalies Research Activities began in September 1980.

Information from each evaluation is intended for use in planning, budgeting, and program management decisions. Information gained from the evaluation completed in 1976 has been used to plan for new initiatives for periodontal research, such as the

specialized clinical periodontal research centers, and for more balanced budget allocations to support such efforts. Information resulting from the Evaluation of the National Caries Program has resulted in the incorporation of the scientific recommendations into new plans for the program, a standardized method for reporting all supported projects, the establishment of a formal planning process, and the refocusing of the cariology training programs. Also, as a result of the evaluation, the National Caries Program has restructured Strategy Area II (Increase Tooth Resistance) and has increased personnel in Strategy Area III (Modify the Diet) in order to promote research in that area.

During FY 80, Stage 1 of the evaluation process has been accelerated. Program goals and objectives as well as performance indicators (evaluation criteria) have been developed for the Pain Control and Behavioral Studies, Restorative Materials, and Soft Tissue Stomatology and Nutrition areas. These objectives have been arrayed along with those previously developed for the Periodontal Diseases, Caries, and Craniofacial Anomalies areas in a Draft Compendium of NIDR Research Goals and Objectives. This Compendium is providing the basis for the development of a five-year Long-Range Plan for the Institute. The Plan is being developed in FY 81 with the guidance of a Long-Range Plan Coordinating Committee. Employing the professional judgment of the Institute staff, the advice of the National Advisory Dental Research Council, and our constituent dental research communities, an analysis of the present state of research and the specification of goals and related planned activities for biomedical and behavioral research related to oral health is being coordinated. A final Plan is anticipated by January 1982. Funds to pay for this major planning effort have been requested through the Consultant Services mechanism. During subsequent years, Stage I results and the updating of the Long-Range Plan will be available for the remaining series of program evaluations.

Major Projects Underway or Recently Completed

In September 1980, the Evaluation of the NIDR Craniofacial Research Activities was initiated. To date the panels for this evaluation have convened and begun the review of research projects from 1974 to 1980. Panels on Craniofacial Anomalies and Acquired Defects and on Dental Malrelations are evaluating the research relative to the program goals and objectives. A Main Panel, with representation and input from the two research panels, is reviewing the entire program research activities. A final report is expected by September 1981. Allowing for the review and consideration of the recommendations generated by the evaluation, the Program Performance Summary will be completed March 1982.

The Evaluation of the NIDR National Caries Program recommendations have been reviewed by the program staff and the NIDR Programs Advisory Committee. Their review and utilization of the findings of the Evaluation Report has led to the actions described in the preceding Policy Overview section. A Program Performance Summary will be completed July 1981.

New Projects Proposed

Two new projects are proposed for FY 82 as outlined in the FY 81 Schedule of Program Performance Evaluations. These include the Assessment of Selected Activities Associated with Dental Research Centers and the Evaluation of the Restorative Materials Research Activities. For FY 83 the Evaluation of the Soft Tissue Stomatology and Nutrition Research Activities is proposed.

Discussions on the future of the Dental Research Institutes Program have occurred within the structure of the NIDR Special Grants Review Committee. This Committee serves as the primary review group for grant applications for Dental Research Institutes. Five such institutes have been established since the program was initiated in 1967. During FY 79, these institutes supported 94 collaborative research projects -- receiving support from non-NIH sources as well as from NIH regular research grant and contract mechanisms. While the Committee has expressed its opinion that the existing centers have been productive and have provided invaluable research training opportunities, a need was expressed (March 1980) to re-examine the program with a view toward releasing monies for competition by new institutions. The dilemma for the NIDR in its situation of a no-growth budget is the problem of how to stimulate more such endeavors without destroying, by phasing out support for, existing productive centers. On April 29, 1980, past and present Dental Research Institute directors were convened, the existing objectives were reviewed and clarified, and potential evaluation questions which could be posed to assess effectiveness and/or efficiency were discussed. The results of this discussion and that conducted by the Special Grants Review Committee were presented to the May 1980 meeting of the NIDR National Advisory Council for their consideration. The basic evaluation question that emerged from these discussions asks whether the research environment of the Centers, when compared to similar non-Center, university-based research environments, varies in terms of supporting oral health research of the highest scientific quality and fostering multidisciplinary and interdisciplinary research. It is planned that a citation analysis comparing these two environments should first be administered (FY 82). The results of this preliminary evaluation may be definitive, or lead to other questions that may need to be further evaluated (FY 83).

Proceeding with the program performance evaluations, the Evaluation of the Restorative Materials Research Activities and the Evaluation of Soft Tissue Stomatology and Nutrition Research Activities will follow as scheduled. The methodology to be used in both of these evaluations will approximate that used for the previous two and one ongoing comprehensive program evaluations. The questions to be answered for both these evaluations relate to research progress, factors that have affected progress, key accomplishments, research gaps, areas to be emphasized, areas to be de-emphasized and contributions to biomedical research. The development of the agreed-upon evaluation design will begin in December 1981 and be completed April 1982 for the Evaluation of the Restorative Materials Research Activities. It is anticipated that Program Performance information will become available in September 1983 and that the Program Performance Summary for this evaluation will be completed March 1984. An additional $50,000 is being requested in FY 83 for this evaluation to cover the potential rise in costs.

NATIONAL INSTITUTE OF DENTAL RESEARCH

Evaluation of NIDR Periodontal Disease Research Activity

Definition and Description of Program

For purposes of the evaluation which took place in FY '75-76, all ongoing research related to periodontal diseases (gingivitis, periodontitis, periodontosis or juvenile periodontitis) was assessed. A total of 141 research projects active as of April 30, 1975 were included, involving $10.7 million. These projects were administered by three major NIDR programs: the extramural Periodontal Diseases Program, the Intramural Program, and the programs of the five NIDR Dental Research Institutes/Centers.

Evaluation Study Performed

Description of Study Design

Peer review or expert judgments of knowledgeable scientists (N=10) constituted the approach to assessing projects in four major research areas: periodontal tissue structure and metabolism; periodontal microbiology; inflammation and immune response in periodontal disease; and prevention, diagnosis, and treatment. Evaluation was achieved by comparing project results with a set of objectives and evaluation criteria made available to the panel. Numerical scores were assigned for each project for each of the following variables: scientific quality, potential to meet the objective, scientific achievements, special features (e.g., uniqueness, application to other specific objectives, etc.), priority relevant to program objectives, potential contribution to other biomedical sciences, short-term payoff, long-term payoff.

Results of Data Analyses

Program strengths: Projects contributed to knowledge on the etiology of periodontal diseases, connective tissue and to the understanding of immune responses. Other strengths include the high scientific quality of many of the research projects and that a number of outstanding scientists have been attracted to periodontal research.

Program weaknesses: (1) Imbalance with respect to the lack of clinical research and lack of adequate support for research in periodontal microbiology, as well as prevention, diagnosis, and treatment; and
(2) unevenness in scientific quality among research projects.

Recommendations Resulting From the Study

- Continue both extramural and intramural research activity.
- Reorganize NIDR to provide for (1) a central program of basic research relevant to all oral diseases and disorders, and (2) a categorical research program relevant to specific diseases and disorders.
- Expand support for clinical research.
- Expand support for microbiologic studies.
- Submit projects of less than adequate scientific quality for staff review.
- Expand support for research on prevention, diagnosis, and treatment.
- Suggest that other Institutes support research on structure and metabolism of connective tissue.
- Increase support for research on inflammation and immune response in periodontal disease.
- Expand involvement of the NIDR Periodontal Diseases Advisory Committee to facilitate continuing program coordination, balance, and assessment.
- Urge FDA to use reasonable criteria in assessing the safety and effectiveness of new chemotherapeutic antiplaque drugs for testing on human populations.
- Urge continued use of individual research grant mechanisms in preference to contracts.
- Explore composition of study sections and review periodontal research applications to assure representation of clinical research expertise.
- Increase support for periodontal disease over the subsequent 3-year period to $18 million (in 1975 dollars), or 35-40 percent of the NIDR budget.
- Promote cooperative research ventures among different institutions.
- Provide training programs to facilitate the application of basic research to clinical problems of periodontal disease.
- A national targeted program in periodontal disease research is not desirable at this time.

Implementation and Effects

- NIDR continues to support three specialized clinical research centers for periodontal diseases. These centers were started according to recommendations of an ad hoc panel that evaluated the Institute's periodontal diseases activity. Currently the efforts of these centers are evenly distributed between prevention and treatment, microbiology, and immunology.

- The investigators of the three centers collaborate freely on various projects and meet annually as a group to exchange ideas and data. The center at Virginia Commonwealth University has a cooperative agreement with Virginia Polytechnic Institute, and most of the microbiological work of the center is done at the latter institution.

- About two-thirds of the extramural grant funds in the Periodontal Diseases Program are allotted to microbiological and immunological research. Over the five years there has been a continuous increase in support of both these areas of research.

- The program conducted a workshop to increase the awareness of the biomedical research community to the need for diagnostic instrumentation for detecting and measuring periodontal pathology.

- The program is supporting research in innovative chemotherapeutic prevention techniques such as slow release systems for the control of periodontal diseases.

- The program is supporting research in the development of antimicrobials for the prevention of periodontal diseases.

- The Director's Advisory Subcommittee on Periodontal Diseases has continued to assess program balance in the Periodontal Diseases Program. During the past year the subcommittee specifically evaluated the role of diabetes and nutrition in periodontal diseases.

- The program conducted a state-of-the-art workshop on "Surgical Therapy for Periodontitis," which assessed current surgical treatment modalities in this area.

NATIONAL INSTITUTE OF DENTAL RESEARCH

Evaluation of the National Caries Program

Definition and Description of Program

The National Caries Program (NCP) was created by Presidential Initiative in 1971 to develop cost-effective, highly acceptable techniques to meet the needs of the public for dental caries prevention. The program is a targeted effort and as such utilizes grants, contracts, and direct operations: (1) to identify new approaches for caries prevention through investigations of disease etiology and epidemiology, (2) to transform these approaches into practical techniques through applied research, (3) to measure cost, effectiveness, and acceptance of techniques in clinical studies and field trials that model eventual usage, and (4) to demonstrate and encourage widespread employment of those techniques established to be suitable. The program's individual projects are reviewed in the conventional manner: grants by Study Section and Council; direct research by the NIDR Board of Scientific Counselors; and contract concepts, contract requests, and contract proposals by extramural and staff groups. A planning unit functioning under the direction of the Associate Director coordinates the utilization of information for program direction. These plans and major activities and progress are reviewed twice yearly with the NIDR Programs Advisory Committee. The size of the National Caries Program expressed in terms of its FY 1980 budget is $11.6 million.

Evaluation Study Performed

The NCP evaluation addressed both the scientific and the organization/management aspects of the program through use of four scientific panels corresponding to the four NCP strategies, through an organization and management panel, and through a main panel which reviewed the NCP from the perspective of the total program. Each scientific panel assessed progress relative to the objectives of the strategy and identified future directions for the area. The evaluation included the progress of the research in terms of the following: specific accomplishments, potential of ongoing research, the degree of impasse in the area, relevance of the research to other areas of scientific investigation, and the development of recommendations for advancing progress in the area. Evaluation of each strategy included scaled assessments, as well as detailed qualitative descriptions of the bases for the panel's judgments.

The Organization/Management Panel employed a number of resources to provide information relevant to management issues posed by the Institute Director. These resources included structured interviews with current and former NCP staff, NIDR senior staff, NCP/NIDR advisors, and others in the Federal Government and outside; program data, including NCP's budget and management processes; and informal presentations by and discussions with key NCP and NIDR staff.

The Main Panel's evaluation of the NCP integrated the evaluations of the four scientific panels and the Organization/Management Panel and concluded with recommendations for future directions for the NCP.

The Main Panel's recommendations were presented from the perspective of the scientific directions of the NCP; mechanisms for stimulating caries research; program organization and management; and budget and resources. The scientific area recommendations included refocusing the NCP strategy hierarchy with a major restructuring of Strategies II, III, and IV to encompass the research needs, opportunities, and future directions of the program. Specific areas of emphasis were mentioned relative to Strategies II, III, and IV. Among major recommendations addressing mechanisms for stimulating caries research were establishment of cariology units, refocusing and expansion of the NCP training program, establishment of a program to provide dissertation grant support, and more active promotion of research opportunities in the NCP. Program organization and management recommendations included restructuring of the program organization to correspond to the NCP's strategy hierarchy; establishment of an epidemiology and biometry area; expansion of the NCP staff in areas of Strategy III and IV; establishment of an interagency committee to facilitate the coordination of the dental caries-related activities of all Federal agencies; establishment of a standardized method for project reporting and of a formal planning and evaluation process; and the review of the status and limitations of the NCP facilities. Finally, for budget and resources, the expansion of the NCP budget to meet the above needs was recommended.

All recommendations were reviewed by the NCP staff and the NCP Advisory Committee in light of the relationship of NCP to other programs within NIDR in this time of economic constraint and scarcity of resources. Several recommendations resulted in the adoption of actual changes. Other recommendations were adapted or led to the maintenance and increased emphasis of existing activities. A few recommendations, such as restructuring of the NCP to correspond to the strategy hierarchy, were not considered feasible at this time. The NCP rationale for actions taken included a discussion of the program's actual and perceived needs and opportunities for each recommendation as it related to the scientific, programmatic, training, and budgetary environment.

Implementation

The implementation process is still ongoing. The sequence of events to date has been as follows:

- Draft copies of the Evaluation Report became available in October 1979.
- During December 1979 all NCP staff participated in a retreat to discuss the recommendations and incorporate them into NCP plans.
- A report generated from this retreat was reviewed by senior NCP staff in February 1980.
- In July 1980 the published report was distributed by the NCP to its Advisory Committee for review.
- In November 1980 this committee discussed the report and the NCP's responses.

The following actions were taken on the major recommendations:

- Strategy II has been restructured so that systemic and topical fluorides are combined in a single strategy component.
- Strategy III has been redefined and a component concerned with optimizing dietary intake patterns has been added.
- NCP has recruited a project scientist to expand the effort on Strategy III through contracts.
- A new request has been issued for applications for cariology training grants.
- The program currently has a special expert working with staff on cost/benefit/effectiveness analysis.
- A standardized method for reporting all NCP-supported projects has been implemented.
- A formal planning process within the NCP is being established.

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NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Dr. David P. Rall, Director

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Proposed Budget

		Dollars in Thousands FY 81	FY 82	FY 83
NIEHS 79-301	Evaluation of the NIEHS Environmental Toxicology Training Program	46	--	--
	Total FY 82 Set-Aside Fund Request		$ 0	

Overview of the NIEHS Evaluation Strategy

A. Policy Overview

At the National Institute of Environmental Health Sciences (NIEHS) program evaluation is an integral part of the overall Institute program planning and implementation process. It provides the information needed to maintain an appropriate balance among programs and mechanisms of funding; to set reasonable priorities that reflect the changing nature of environmental health problems; and to identify realistic and meaningful goals for NIEHS activities. Because the Institute views the entire planning and evaluation process as a whole, evaluation results are considered necessary for developing policy and program management decisions and for planning the allocation of research resources to areas of greatest need, importance, and promise.

The following sections of this overview outline the NIEHS program structure and the planning, implementation, and evaluation process, both necessary to understand the NIEHS evaluation activities for FY 1982.

B. NIEHS Program Structure

The NIEHS was created in 1966 to develop an understanding of the interrelationships between chemical and physical factors in the environment and human diseases, and to help translate the knowledge developed into planned actions to prevent or relieve human health problems of environmental origin. From the outset, this broad mission has required the Institute to continually assess and refine its programs in order to strengthen the knowledge base in the environmental health field. For example, in response to the stringency of the budget situation in the early 1970s, this evaluative process resulted in the NIEHS marshaling its resources and more sharply focusing its efforts on fundamental and applied research in selected areas of central concern. It chose to concentrate on chemical factors in the environment, emphasizing studies on the causes of disease and the effects of organic and inorganic chemicals on human health.

Today this process of reassessment and refinement of NIEHS programs continues, and has been affected by two recent developments: the establishment of the National Toxicology Program (NTP) and the recommendations of the Program Planning Work Group. Briefly, the NTP was established by the Department of Health and Human Services (DHHS) Secretary in 1978 to strengthen the Department's activities in the testing of chemicals of public health concern, as well as in the development and validation of new and better integrated test methods. The NIEHS Director serves as NTP Program Director and is responsible to the Assistant Secretary for Health, DHHS. The Program Planning Work Group was established by NIEHS in 1978 to convert the wide-ranging report of the Second Task Force on Research Planning in Environmental Health Science to a set of focused recommendations for the Institute's program planning. As had earlier planning groups, this work group recommended that the proper role of NIEHS spans the entire continuum of biomedical research, from basic research to applied research to application.

With the development of the NTP, the responsibility for performance of bioassay testing for carcinogenic, mutagenic, and general toxicity, and the associated responsibility for test validation and protocol development that provides information required for controlling hazardous chemicals, is identified with the NTP. This development has permitted the NIEHS intramural and extramural programs to focus on the critical task of developing knowledge of how environmental chemicals damage biological processes, how this damage can be detected and characterized at the molecular as well as the organismal level, and how this spectrum of knowledge can be incorporated into biological assay systems that define toxicity. Figure 1 provides a simplified depiction of the interaction among the various NIEHS program elements.

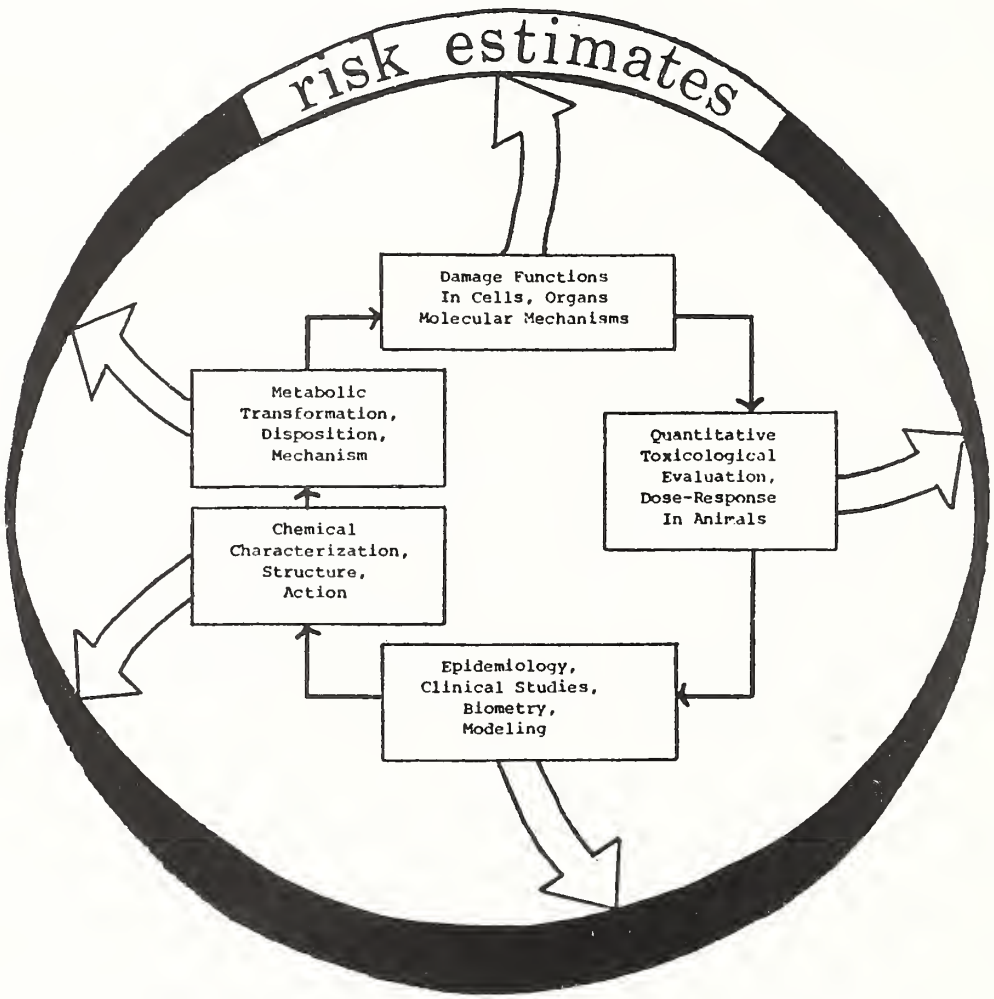

Figure 1: Interaction Among NIEHS Program Elements

Building on this interaction among its program elements, NIEHS has developed a balanced program of basic research, developmental and applied research, health risk estimation, and information and technology transfer. The NIEHS intramural and extramural research programs serve as links

between the study of chemical disruption of fundamental biological processes and the utilization of this knowledge in the applied toxicology systems validated and used by the NTP. The information derived from this fundamental and applied toxicological research is supported where possible by epidemiological studies in human populations. It is from this spectrum of research activities that risk, or the likelihood of disease in human populations, is estimated. The knowledge that flows from this process is used by the scientific community, government agencies, the health care delivery system, and industries which now have defined responsibilities for characterizing toxic substances. This information also is provided to Congress, public interest groups, and concerned citizens.

Figure 2 provides a generalized portrayal of this research continuum. Although it touches on the underlying logic of the process, it misses a key element: the process is complex, dynamic, and interactive. The program elements are overlapping although diverse; and they benefit from contributions of the scientific community throughout the world. Moreover, each scientific advance does not necessarily progress through each phase of the process in the order shown. There are many possible entry and exit points, with evaluative information fed back to earlier phases of the research continuum.

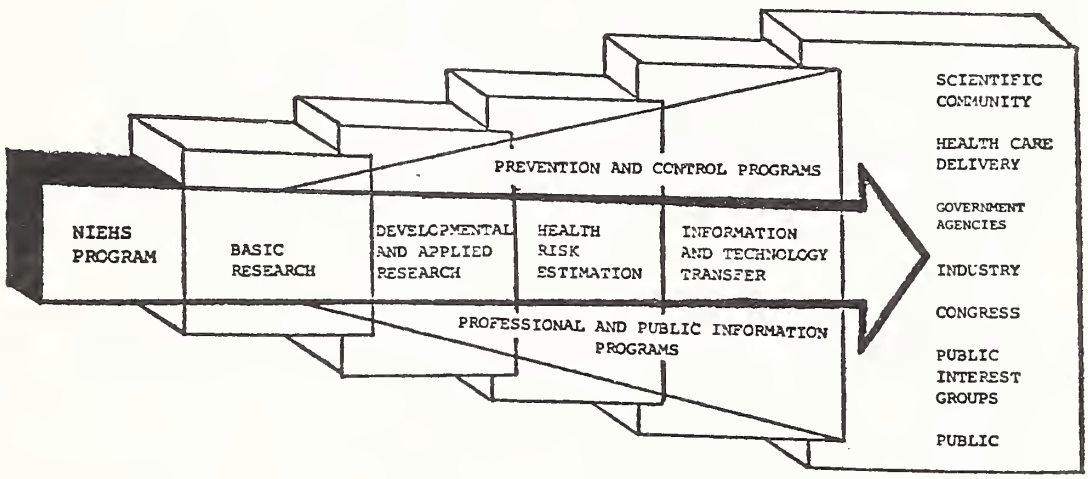

Figure 2: NIEHS Biomedical Research Continuum

For program management purposes, NIEHS research activity is subdivided into the following categories, based on the development of the NTP and the Program Planning Work Group recommendations:

- Characterization of Environmental Health Hazards
- Biological Response to Environmental Health Hazards
- Applied Toxicological Research and Testing
- Biometry and Risk Estimation
- Intramural
- Resource and Manpower Development

Each of the program areas may involve activities from basic research to information dissemination.

C. Planning, Implementation, and Evaluation Process

Because the Institute views the entire planning, implementation, and evaluation process as a whole, the development of NIEHS evaluation plans occurs in parallel with the development of the Institute's planning and implementation documents. Evaluations then are conducted in a variety of ways, ranging from project reviews through individual program evaluations to assessments of the overall Institute program, in order to support management at all levels in the program.

In carrying out its evaluation program, NIEHS relies to a great extent upon its formally constituted non-governmental review groups, the National Advisory Environmental Health Sciences Council (NAEHSC) and the Board of Scientific Counselors. In addition, the NIH-wide scientific peer review process serves as an integral part of the Institute's program evaluation system.

But NIEHS also has developed procedures for vigorous internal review and evaluation of its ongoing research programs. Annually, in the summer preceding the upcoming fiscal year, budget allocations and subsequent year budget requests for each intramural research work group are reviewed by the Scientific Director. These reviews are conducted with the laboratory chiefs and the research scientists on an interactive basis. The accomplishments and productivity of each research group are reviewed in the context of Institute research objectives. The research's direction and resource needs in the upcoming and subsequent years are examined in terms of its importance to enlarging the body of scientific knowledge and to advancing program objectives and priorities. It is in this setting that evaluative judgements are brought to bear upon implementing the planning process.

Within limits set by the Congressional appropriations process and Administration policy, the Institute Director, Scientific Director, and Associate Directors determine a budget level for each program activity that reflects judgements made in the processes of planning, peer review, and internal management review. These processes are iterative and represent feedback loops that inform management decisions; they also are influenced by the continuous flow of information from the public, the medical and scientific communities, other Federal agencies, and non-Federal organizations. These processes are carried out primarily without evaluation set-aside funds, which are used to augment the basic planning and evaluation cycle as needed. Table 1 on page 12.7 outlines this NIEHS evaluation process.

Recently Completed Evaluation

During FY 1981, the Office of the Assistant Secretary for Management and Budget (MB) undertook a management review of the NTP to assist the Secretary in deciding whether or not to make the NTP permanent. When the NTP was established by the Secretary on November 15, 1978, it was perceived as an experimental response to a long-term and continuing problem: namely, how to strengthen DHHS' activities in the testing of chemicals of public health concern, as well as in the development and

TABLE 1: NIEHS Evaluation Activities

Evaluation Activity	Program Elements Addressed	Evaluation Objectives	Frequency	Fiscal Support Mechanism	Product
NAEHSC Review	Overall NIEHS Program	Assess NIEHS programs and research needs in field of environmental health	About every 8-10 years	Operating funds	Task force reports to NIEHS Director
NAEHSC Review	Overall NIEHS Program	Assess grant applications for research and training, recommend approval of those with high program relevance and merit	Three times per year	Operating funds	Recommendations to NIEHS Director
NAEHSC Centers Subcommittee Review	NIEHS Center Programs	Assess adequacy of management and quality of research and training	Semiannually	Operating funds	Recommendations to NAEHSC and to NIEHS Director
Board of Scientific Counselors Review	NIEHS Program Areas	Assess program research progress, identify needs, recommend program actions	Semiannually (each program area at least once every 3 years)	Operating funds	Reports to NIEHS Director and Scientific Director
NTP Board of Scientific Counselors Review	NTP Program Areas	Assess program scientific content, identify needs, recommend program actions	Three times per year	Operating funds	Reports to NTP Executive Committee and Program Director
Peer Review	Research, Training, Program Project, and Center Grant Applications and Contracts	Assess scientific merit of applications and contracts	Three times per year	Operating funds	Rating of applications and contracts
NIH Director's Review	Overall NIEHS Program	Assess NIEHS program progress, identify needs, recommend program actions	Annually	Operating funds	Report to NIEHS Director and budget allocation decisions
Scientific Director's Review	Each Intramural Research Group	Assess accomplishments, productivity, research direction, and resource needs; recommend alternative program actions	Annually	Operating funds	Report to NIEHS Director, input to program planning and implementation, budget allocations and requests
Focused Evaluation Projects	NIEHS Programs and Program Components	Assess program progress and effectiveness, establish or refine goals	As needed	Set-aside funds; operating funds as required	Reports to NIEHS program management and staff

validation of new and better integrated test methods. Thus, its organizational structure--which involves NIEHS, NCI, FDA/NCTR, and CDC/NIOSH* dedicating resources to the program each year; a Program Director to manage the resources; and an Executive Committee to advise and monitor the program--represented the least formal arrangement possible.

Following its review, the MB study team reported it found indications of initial success by the NTP in moving toward each of its goals. Specifically, progress has been made in expanding the number of tests, especially in the short-term testing area; in broadening the scope of the tests, especially in the long-term test area; and in developing standard protocols. The study team also indicated that the long-term nature of the goals of the program and the newness of the NTP made it impossible to evaluate definitively the NTP on the basis of end results achieved during its 20-month existence.

For this reason, the MB study team turned to an identification and assessment of process goals to gauge the potential of the present organization to meet its mission. The study team selected three broad process goals to assess the performance of NTP: consensus building, guidance issuance, and operational responsiveness. In terms of tangible end results, the study team found that the special set of organizational arrangements known as the NTP has resulted in some progress being made in the management of toxicological activities. Three indicators of this progress are: (1) the development by NTP of a list of chemicals that have been thoroughly reviewed and selected for testing, (2) the prevention of duplicative testing of chemicals by DHHS and other governmental agencies through the interaction encouraged by NTP, and (3) the establishment of a single organization within DHHS to serve as the repository for chemical testing information and a source of consultation on issues relating to chemical toxicology.

Based on its findings, the MB study team recommended that NTP's experimental designation be removed and that NTP be established as the permanent mechanism for coordinating the Department's toxicological research. The study team expressed its belief that, because some form of coordinative mechanism must be used, the NTP--with some modifications--offers the highest probability for success because of the experience it has gained and the relationships it has developed over the two years of its existence.

Among the managerial or procedural changes the study team suggested the NTP Program Director make is the development of a comprehensive NTP-wide systematic follow-up mechanism, or management information system, for tracking operational objectives. Although the NTP does have an initiative in the DHHS Operational Management System (OMS), it is not specific enough to guide day-to-day operations. In addition, its quarterly reporting cycle does not permit timely problem identification or corrective actions to take place.

The study team concluded that steps should be taken to improve the ability of the Program Director and Executive Committee to set program

* National Cancer Institute (NCI); Food and Drug Administration/National Center for Toxicological Research (FDA/NCTR); and Centers for Disease Control/National Institute for Occupational Safety and Health (CDC/NIOSH)

direction in more specific terms and monitor progress and problems against the agreed-upon direction on at least a monthly basis. Without threatening the judgmental prerogatives of scientists conducting individual tests, the study team concluded that the NTP must tighten its operational planning and control systems if it is to respond as efficiently as possible to the almost certain increased demand from Congress and the public for NTP performance.

FY 1982 Evaluation Activities

During the coming year, NIEHS program managers and staff will continue to rely on the NIEHS evaluation process (previously depicted in Table 1) for assessing the effectiveness, responsiveness, and contribution of Institute programs. Also, discussions are underway with NTP program staff to determine if a project in the early planning stages might be proposed for set-aside funding. Project plans are too tentative for inclusion at this time, but they will be submitted as a supplement to the FY 1982 NIEHS Evaluation Plan if the decision is made to proceed with the project.

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Analysis of Paraquat and Its Degradation Products in Smoke From Paraquat-Contaminated Marijuana Cigarettes

Background

In 1975, the Mexican Government--with support from the United States--began aerial spraying of herbicides, principally paraquat, on marijuana plants. In 1977 and 1978, concern arose in the United States that paraquat-contaminated marijuana was entering the country and might present a health hazard. In response to this concern, Congress passed Section 4 of the International Securities Assistance Act of 1978. This statute provides that assistance under the act may not be provided for any program involving the spraying of a herbicide to eradicate marijuana if the use of the herbicide "is likely to cause serious harm to the health of persons who may use or consume the sprayed marijuana," unless a marker is employed that will "clearly and readily warn the potential users" of the herbicide. It also directs the DHEW Secretary to advise the Secretary of State if such use of a herbicide is likely to cause serious harm. If he is so advised by the DHEW Secretary, the Secretary of State is required to determine whether a suitable marker exists. If such a marker cannot be found, the Secretary of State must discontinue U.S. financing of any marijuana eradication program that involves use of the herbicide.

When the DHEW Secretary was informed that the Mexican program involved the use of paraquat, he was required to investigate the health consequences of consuming paraquat-contaminated marijuana. He requested the assistance of the National Institute of Environmental Health Sciences (NIEHS) and the Center for Disease Control (CDC). NIEHS was directed to test marijuana cigarettes contaminated with different concentrations of paraquat to determine how much unaltered paraquat remains in smoke condensate. The CDC was to undertake a systematic sampling program designed to obtain the best information possible about the prevalence of contamination of marijuana in the United States and the distribution of concentration levels in such marijuana.

The NIEHS project was performed under contract by the Research Triangle Institute (RTI) and was supported through the evaluation set-aside program; $173,000 was funded during FY 1979. The goal of this project was to provide the necessary analytical data to assist the DHEW Secretary in evaluating any potential hazards of smoking paraquat-contaminated marijuana in the United States. Together, the results from the NIEHS and the CDC studies would help the Secretary assess the degree of actual or potential risk to humans.

Evaluation

Design of Study

Several types of marijuana preparations containing paraquat were analyzed. These included confiscated marijuana containing various levels of paraquat as a consequence of aerial spraying, marijuana coated with known levels of radiolabeled paraquat by mixing the labeled material with marijuana, and marijuana sprayed with paraquat in an attempt to simulate aerial spraying. The samples of marijuana were combusted on either the RTI combustion apparatus, the North Carolina State University (NCSU) cigarette smoking machine, or the Borgwalt cigarette smoking machine. Smoke condensate from the combustions was analyzed for paraquat and 4,4'-bipyridine content. A mass balance experiment using ^{14}C-paraquat-sprayed marijuana was carried out to determine whether marijuana smoking parameters are similar to cigarette smoking parameters.

Results of Data Analyses

- The amount of paraquat in smoke condensate varies, depending on how the contaminated marijuana samples are prepared, their level of contamination, and how they are burned.

- Marijuana smoking parameters, although varying widely from person to person, are quite different from cigarette smoking parameters, so that only generalized conclusions can be drawn from studies using cigarette smoking parameters.

- Nevertheless, it is clear that a person smoking a marijuana cigarette contaminated with paraquat would receive a low, but finite, dose of unchanged paraquat.

These findings, when evaluated with the results of the CDC sampling program, led to the NIEHS-CDC joint conclusions that:

- The smoke of paraquat-contaminated marijuana is likely to cause serious and in some cases irreversible lung damage when inhaled in sufficient quantities by some marijuana users.

- There is a direct relationship between the amount of paraquat inhaled and the extent and severity of lung damage. Lung damage from intermittent or short-term exposure may be reversible, but frequent, high-level exposure over a long period of time can result in a severe form of damage called fibrosis.

- Significant numbers of people, particularly in the southwestern United States, are likely to be subjected to varying levels of harm and, in some cases, serious harm.

Organization Response to Recommendations

On the basis of the information provided by the NIEHS and CDC projects, and comments received from the Secretary of Agriculture and the Administrator of the Environmental Protection Agency, the DHEW Secretary advised the Secretary of State in 1979 that the spraying of marijuana with paraquat is likely to cause serious harm to the health of some persons who may use or consume the sprayed marijuana. At that point it became the responsibility of the Secretary of State to determine whether a suitable marker exists to warn of the presence of the herbicide. Nevertheless, the DHEW Secretary offered the assistance of the Department in the design, evaluation, and interpretation of tests to determine the effectiveness and safety of any marker. If a safe and effective marker could not be identified, assistance under the International Securities Assistance Act of 1978 could not be provided by the Secretary of State for any program--including the Mexican marijuana eradication program--that involves the spraying of paraquat to eradicate marijuana. Currently, legislation to repeal or amend Section 4 of the International Securities Assistance Act of 1978 is before the House and Senate.

Reference

"Combustion of Paraquat-Contaminated Marijuana--Analyses of Paraquat and Its Degradation Products," Final Report of the Research Triangle Institute, Research Triangle Park, N.C., on Evaluation Project NIEHS 79-302, Contract 273-79-C-0003, August 1981.

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NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

Dr. Ruth L. Kirschstein, Director

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Proposed Budget

		Dollars in Thousands FY 81	FY 82	FY 83
NIGMS 79-401	Evaluation of Medical Scientist Training Program	(5)	--	--
NIGMS 80-401	Evaluation of MARC Faculty Fellowship Program	(5)	--	--
NIGMS 80-402	Evaluation of Research Career Awardees	(1)	--	--
NIGMS 81-401	Evaluation of Genetics Program Performance	(30)	--	--
NIGMS 81-402	Evaluation of the Impact of the NIGMS/OMAR Consensus Development Conference on Supportive Therapy in Burn Care	(10)	(5)	--
NIGMS 82-301	Evaluation of Human Genetic Mutant Cell Repository	--	100	--
NIGMS 82-401	Evaluation of Shared Instrumentation Initiative	--	(5)	--
	Total Set-Aside Fund Request		$100	

Notes: ( ) non set-aside funds

Policy Overview

The principal mission of the National Institute of General Medical Sciences is to help create, through support of basic research, the knowledge base from which medical applications and disease prevention strategies can emerge. The Institute also provides support for the training of research manpower to assist in meeting the Nation's continuing need for well-trained biomedical scientists. To accomplish this, the NIGMS is organized into five scientific programs: four of which, Cellular and Molecular Basis of Disease, Genetics, Pharmacological Sciences, and Physiology and Biomedical Engineering, support both research and training, and one, the Minority Access to Research Careers Program, concentrates exclusively on training. Although the various activities supported by the NIGMS are organized into these program areas for administrative purposes, the majority are, in reality, a unified and interdependent effort since they deal with fundamental life processes which are not compartmentalized.

Although the basic science support programs of the NIGMS cannot be said to have targeted endpoints as such, the quality of these activities is the goal, and evaluation needs to be addressed to the maintainence of the highest level possible. Consequently and whenever possible, the evaluation projects of NIGMS are intended to apply across program lines and help guide them along the most fruitful directions.

Evaluation occurs at various levels, ranging from studies of individual initiatives, such as that proposed for the Human Genetic Mutant Cell Repository, to broad-ranging reviews of entire programs, such as those conducted periodically by the National Advisory General Medical Sciences Council. Also, in a practical sense, program evaluation, as it is carried out by the peer review process of the Division of Research Grants, is another continuing, all-pervading evaluation process. Here, every application for NIGMS support is first reviewed by panels of experts who apply their own current knowledge of the field, of other ongoing research, and of the importance of the problem being addressed. In this way, each and every research and research training project is screened in advance for its feasibility and promise -- an evaluation in advance. Support is usually limited to a three-year span, so that a timely and periodic re-evaluation of the project's performance and outcome can take place.

In recent years, the NIGMS has not needed to make direct use of the evaluation set-aside to assess its basic scientific research programs. The decisions to emphasize and encourage certain scientific fields within the Institute mission are influenced by Congressional interest, Council input, and staff judgment. The latter is guided by evaluations by consultants, individually or in workshops, who have the expertise to identify scientific opportunities that have not attracted sufficient attention from potential applicants. Conversely, the consultants may indicate fields that have generated too much attention and where research grant support appears to be saturated or "overcommitted."

As mentioned, the Institute Advisory Council has a broad view of the Institute's programs and examines each program in detail, periodically. All of the above have been used to assess program balance, identify scientific

opportunities, and fine-tune the allocation of resources. In the past, set-aside funds have been used to support the development of evaluation methodology and for manpower and training studies.

Currently, as the Institute Summary shows, three evaluation projects are in their final stages, one is in progress, and three new ones are being proposed. In general, there is a common use to which each of these studies will be put -- and it is this: The majority of the Institute's programs deal with research and training in the fundamental life sciences, which are essentially a class of "equals." There is no formula or guide beyond periodic assessments of quality that can be used to adjust balance among these equals, or to place emphasis on some and not others. Thus, the principal purpose of each evaluation project is to examine a larger or smaller segment of the Institute's programs from the point of view of its quality and the extent to which it is fulfilling the original intention that led to its undertaking. Further information on each of these projects is provided below.

Major Projects Underway

The following current evaluation projects will be used to adjust programmatic emphasis and balance.

(NIGMS 79-401) The Medical Scientist Training Program

This program was designed to provide highly qualified students with a rigorous education in basic science combined with broad training in clinical medicine. Since its beginning in 1963, the program has maintained rigorous standards and has grown slowly. Preliminary evaluation of its graduates has been carried out. An analysis of the number of graduates of this program who are doing research, the nature of their employment settings, and the character of their publications and research grant support is being made. The outcome of this evaluation will provide information that will be used to determine: (a) whether the objectives of the program are being met, and (b) at what priority and level of funding the program should continue.

(NIGMS 80-401) The Minority Access to Research Careers Faculty Fellowship Program

The objective of this program is to strengthen biomedical research and teaching at colleges and universities with significant minority enrollment. Faculty members at these schools are nominated to spend 1-3 years at a major graduate school, either to complete a doctoral degree or for postdoctoral study. It is intended that they then return to the nominating school. The purpose of the evaluation study is to determine the success of the program in terms of: (a) the proportion of the fellows who return to the nominating institution, (b) evidence for the effectiveness of the research training, e.g., publications or grant support, and (c) impact on the minority institutions. If the evaluation of the MARC Faculty Fellowship Program shows that a satisfactory proportion of the fellows are fulfilling the stated objectives of the program, in the judgment of the Institute staff and Advisory Council, the Institute would continue to give priority to that program in future years.

(NIGMS 80-402) The Research Career Awardees

This study was undertaken to measure the productivity of the recipients of the Research Career Awards (K06) which were made in 1961-1964 by tracing their subsequent grant support and bibliographic history to establish the ability of the recipients to obtain research support after receiving the K06 award. A bibliographic data search was made and a list of publications of each recipient documented. The impact of their citations is also being evaluated in terms of the journals in which the manuscripts are published. Similar information is being obtained from control peer populations.

(NIGMS 81-401) The Genetics Program

Phase I of a two-phase evaluation of the genetics program is underway. The purpose is to develop a clearer understanding of the extent to which genetics research is pursued and funded by the various NIH programs and of the relationships of the NIGMS Genetics Program, designated the lead genetics activity at NIH, to these other activities. The output of the survey will be published as a first attempt to provide a coherent overview of genetic activities for use by NIH managers, extramural scientists, other Federal agencies, and the Congress.

Phase II will use the data generated in the NIH-wide survey as the major component of a program performance evaluation. Input from NIH-wide activities is required for this evaluation as the NIGMS Genetics Program is considered as a concept generating and undergirding component of NIH-wide research activities in genetics. Accordingly, any evaluation of the NIGMS program must be done in the context of its relationship to the larger effort.

New Projects Proposed

(NIGMS 82-401) Evaluation of Shared Instrumentation Initiative

Key factors in the success of any scientific program are the availability of well trained research manpower and sophisticated instruments. There are many examples where the lack of one or both of these limits progress in a field. Within certain administrative constraints, the Institute tries to remove such bottlenecks; with limited budgets, it is essential to identify and focus on the most critical shortages.

To this end, in February 1978, the Institute convened a meeting of consultants, who affirmed the fact that a real need existed for Institute grantees to obtain and update major items of scientific equipment related to their projects. Typically, a piece of research equipment has a useful half-life of six to eight years. Most major laboratories and investigators acquired major equipment items in the middle or late 1960s, at which time approximately 16-18 percent of the direct costs were earmarked for equipment. Since that time, in the face of limited funding, this percentage has decreased to 7-8 percent and much of the equipment in use is nearing obsolescence. Last year, on the basis of this review, the Institute offered a competitive grants program to Institute and NIH-supported scientists who agreed to

share such major equipment (typically ranging in cost from $40,000 to $200,000) with other scientists locally. This grants program has become a yearly offering, with one deadline per year. When these grants have run for 3 years, the Institute plans to summarize how the pieces of equipment were used and how they benefited the users. It is estimated that this project will cost approximately $5,000 in FY '82 paid from in-house funds.

(NIGMS 82-402) Evaluation of Human Genetic Mutant Cell Repository

The NIGMS Human Genetic Mutant Cell Repository was started in 1971. To date, no evaluation of its effectiveness as a resource to the scientific investigative community has been performed from the perspective of the basic science research it facilitates. The increasing number of cell lines collected and distributed, the high quality of the samples supplied, and the satisfaction of cell line users indicate that the cell bank is meeting a need of the scientific community, that the product is of high quality, and the mechanisms of gathering, establishing, characterizing, storing, and distributing human mutant cell lines are sufficient.

There are difficulties in designing a study for evaluating the effectiveness and the impact of the cell repository, since clearly understood and stated goals for "success" are ambiguous. In this evaluation, among the questions the Institute can ask is "What important results can be traced to research using cell lines provided by this cell bank?"

A computer-aided bibliographic search comparing the names of the people who received cell lines and the articles they have published and where they were published will be done. These searched publications will then be compared to all publications in a specific field from the same year of request. The number of times the cell lines bank is cited will be verified and the journal rating will be noted. This information will be tabulated and evaluated.

The number of publications citing use of the resource will be another way of gauging "success." If substantial numbers of those who requested cell lines actually have approved grants (citing the cell lines), then the remaining might be surveyed to find what they did with the resource material, e.g., graduate research teaching. The list of requestors and their NIH Institutes will be put into a format which will allow direct access to the DRG IMPAC system. A list of grants with priority scores and funding levels will be generated and ranked. In this way, the effect of such a resource on the broad-based basic science research will become self-evident. It is estimated that this project will cost approximately $12,000 from in-house funding in FY '82.

(NIGMS 82-403) Evaluation of the Impact of the NIGMS/OMAR Consensus Development Conference on Supportive Therapy in Burn Care

The NIGMS has supported research on burn injuries for the past 15 years. Although much about treatment for burns has been learned, there still is much that is unknown regarding the basic mechanisms of the response of the body to burn injury and what is the best treatment. In November 1978, the NIGMS, with the cooperation of the American Burn Association and the NIH Office of Medical

Applications of Research, sponsored a Consensus Development Conference on Supportive Therapy in Burn Care. The participants in this conference were able to reach consensus in a number of areas that directly affect the type of treatment provided to severely burned patients. In addition, several approaches to treatment and technologies that appear promising were identified. The Consensus Development Conference conclusions were distributed as widely as possible to the medical profession and those interested and were published in The Journal of Trauma as a supplement to the November 1979 issue.

This program performance evaluation is being done in two phases. Phase I involved the sponsoring of a Second Conference on Supportive Therapy in Burn Care, which was held in October 1980. Although the same topics were addressed, presentations included new work in an effort to validate the former recommendations. Further, the participants identified and discussed the areas in the clinical management which need further exploration. Additional goals of this second conference were: (1) to review the impact of the results of the Consensus Development Conference on the medical community and its management of burn patients, (2) to review the NIGMS trauma and burn research and research training activities, and (3) to recommend ways to assure adequate dissemination of the conference results. The proceedings of the second conference are in press and will receive the same wide distribution as the Consensus Development Conference, i.e., to the medical profession and interested members of the public.

Phase II involves a study of the impact of the Consensus Development Conference recommendations on the treatment and management of the burned patient, i.e., in particular to reduce mortality and morbidity in these people. It appears that the original conference proceedings are referred to extensively and repeatedly by clinicians who care for this kind of patient, and it is necessary to see if the recommendations of these conferees have made a difference in the practice of burn medicine. A survey of the treatment practices at the six burn demonstration sites of the HSA's Division of Emergency Medical Services will provide a strong data base for the impact study. These sites were chosen because (1) they were set up as EMS models to demonstrate the use of the best burn care technology available and are, therefore, the most likely settings for the Consensus Conference results to have their first impact; (2) a considerable amount of background information was already available; and (3) they lend themselves easily to study. Estimated cost for this project in FY 82 is $5,000 from in-house funds.

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

Evaluation of the Study on the Application of Bibliometric Methods to the Analysis and Tracing of Scientific Discoveries

Description of Contract Evaluation Study

This contract was for the purpose of determining whether bibliometric methods could be used to trace the development of scientific research. In particular, an attempt was made to follow the transition from basic research to clinical applications in several areas of research. The work was performed by the Institute for Scientific Information (ISI), Philadelphia, PA. and directed by Henry Small.

Evaluation Study Performed

Description and Results:

Three models were developed: (1) the studies on Lesch-Nyhan syndrome, (2) Tay-Sachs disease, and (3) the application of the drug methotrexate to treatment of leukemia. Two approaches were used. The historiographic approach traced direct reference connections among selected key papers in a field. The progression of the field was then revealed by the citation links. The other approach utilized cocitation analysis, which relies on the co-occurrence (cocitation) of citations rather than the direct citation of one paper by another. This produces a "cluster" of papers with elements in common. For the purposes of this contract, the historiographic approach is the more significant.

An initial difficulty was the need to define each publication as either clinical or basic. Three criteria were used to define a clinical paper: (1) The paper deals with human disease, (2) the paper mentions procedures involving "human subjects," "cases," or "patients," and (3) the work described uses materials obtained from human subjects. A basic paper would have all three criteria not applicable. A third category, described as "mixed," would involve the utilization of both human and nonhuman materials, usually from a biochemical viewpoint.

It is clear that this method of categorization is not completely satisfactory. It is also clear that no approach which applies a priori criteria will be altogether satisfactory. In fact, only a consideration of the in-

tent of the author(s) would be an optimal mechanism for classification, and even this has its shortcomings. In the end, the problem of basic/clinical labeling is an intrinsic limitation to any study of this kind, and the errors generated by the method of classification must be understood and accepted. In this study, it seems likely that the clinical category is overdefined (from criterion #3), and there will be "clinical" papers that would be more appropriately described as "basic."

In the historiograph data sets, there are one (or more) papers that are defined as "discovery" papers. There are also single papers in each case that are defined as "nodal," i.e., they are the first applications of the basic research to the relevant clinical model. The discovery paper(s) is traced forward in time by tracking all the papers which refer to it. A "second generation" would be all the papers which refer to these papers, etc. To keep these populations from being unmanageably large, only papers which were themselves cited a large number of times were recorded. A consequence of this process can be seen in the Lesch-Nyhan study, where this restriction prevented the nodal paper from showing up on the trace from the discovery paper. This is due to the fact that the paper linking the two is itself cited less than cut off frequency imposed on the process.

Two other trace procedures were used. One starts with the nodal paper and traces forward. The other starts with the nodal paper, traces forward one generation, and then back one generation. Although some significance was attributed to the basic/clinical mix produced, it is not clear just what such trace procedures reflect. Consequently, these results will not be described further.

In summary, only the Tay-Sachs analysis shows any convincing transition between basic and clinical. Many reasons can be generated, of course, to explain the failure in the other cases. One certainly is that (arbitrary) application of a citation level eliminated papers that were critical links between basic and clinical studies, although they themselves are not considered of major importance, at least as reflected by the number of times they are cited. In other words, these papers may be important as catalysts, for whatever reason. One possibility might be a publication in a journal widely read by clinical investigators, which provided the important references to the biochemical literature. This paper need not itself have made a large substantive contribution to literature. This is actually an intriguing idea. If substantiated (and there are some ways this can be approached), it would provide further justification for funding the swordbearers of the scientific community.

Another possibility is that the wrong "discovery" paper was used. However, this seems less likely, since any reasonable starting point converges rapidly to the same population of papers.

Recommendations:

The cluster analysis is perhaps potentially more rewarding, since it shows the linkage of different areas of research at any given point in time. How-

ever, the cases evaluated already had undergone a transition from basic to clinical at the earliest date that clusters could be compiled. Thus, the specific aim of determining the progress of such transitions could not be evaluated.

Implementation

In summary, the results obtained are more evocative than conclusive. The anecdotal questionnaires provide some supporting evidence for the validity of the historiographic maps, but they also emphasize how much was missed. As the authors note, tracing backwards from a recent key publication may be the best approach. However, this is a costly procedure. Before any further exercise is attempted, consideration must be given to the possible uses of such data. Certainly it has value as a historical tool, or to showcase the contributions of some of our grantees. As a management tool, its value is less apparent. There was, therefore, no implementation of any policy or procedure as a result of this evaluation study.

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

Evaluation of Nontenure-Track Personnel: Opportunities for Independent Research

Background and Description

This project was initiated to further analyze data collected in the report "Nontenure-Track Science Personnel: Opportunities for Independent Research" (Higher Education Panel Report No. 39, September 1978, published by the American Council on Education). These data confirm the existence of a substantial population of doctoral-level scientists who occupy nontenure track positions at advanced degree-granting institutions. These data further suggest that, for reasons of policy, tradition, or low expectations, these scientists are only marginally engaged as principal investigators on NIH research grants. It was intended that these findings be brought to the attention of manpower planners and others concerned with optimal utilization of the Nation's research manpower resources in health-related fields.

Evaluation Study Performed

When an analysis was run in 1980, it was discovered that the published report dealt in national averages, and the raw data for the subcategories of potential interest to NIH biomedical research program staff dealt with only very small numbers that were unlikely to be statistically significant. This created serious doubts as to the possible value of any further analysis. The project, therefore, was terminated without using any evaluation funds.

There was no doubt, however, that as an offshoot of the original survey, the attention of university officials was drawn to the subject, and NIH's concern about this research pool had been expressed.

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

Evaluation of Medical Scientist Training Program

Background and Description of Program

The Medical Scientist Training Program (MSTP) was initiated in 1964 under PL 78-410, and since 1974 has operated under the National Research Service Award Act (PL 93-348). Its purpose is to provide support for combined medical and scientific training leading to the joint degrees of M.D. and Ph.D.--ultimately to get M.D.'s with extensive research experience into biomedical research. It was envisioned that many of the graduates would find successful research careers ranging from basic to clinical. Since only a few schools offered such combined degree programs prior to the founding of this NIGMS training program, the MSTP has expanded slowly with funding of only the most meritorious programs. Expansion was deliberately kept slow, but steady, to help ensure the high quality of the trainees. A total of 455 young scientists graduated from the program from 1968 to 1980, with a current yearly output of about 80. This program has been heralded by many groups for its high standards and quality and its role in easing the national shortage of research-trained clinical investigators. There is no basis to doubt these acclaims, but it was felt that since the MSTP has reached maturity in size and scope, a limited evaluation of career selections of the graduates should give some indication as to whether the program is accomplishing its original goals.

Evaluation Study Performed

Design of Study

This evaluation is focused on the 81 graduates of the MSTP from 1968 through 1974. Most of them are in the early stages of their careers. Nevertheless, it has proven possible to draw some guarded general conclusions about their career development. A complete evaluation should include a survey of the graduates as well as several control groups. The present evaluation is more limited in nature, avoiding the expense, delay, and respondence burden necessitated by a more detailed study.

Data on these MSTP graduates were obtained from several sources: (1) the NIGMS official files of the program contain applications, progress reports, and other information from program directors. Information on trainees, both

before and after graduation, was found in all cases. (2) Telephone calls to each MSTP graduate's institution, or in some cases to the graduate directly, were made to obtain current addresses. (3) The NIH IMPAC data file was used to obtain information on applications submitted to the NIH by the MSTP graduates for research grants and research training grants. In addition, the NSF provided a list of research grants awarded to these graduates. (4) The NIH library conducted a literature search using the following data bases: Bio Sciences Information, Chemical Abstracts, Excerpta Medica, MEDLINE, and Sci Search. The number of research publications was obtained for each graduate. Efforts were made to delete duplications, abstracts, letters, and errata.

Results of Data Analysis

From the data gathered, it appears that 56 graduates are currently engaged in research, 23 are in clinical practice, and 2 were not located. The finding that 70 percent of these graduates are still in research needs to be put in perspective. In the absence of directly comparable data, information from several studies was reviewed. In 1973, approximately 80 percent of the graduates of the NIGMS-supported programs (mostly Ph.D. recipients) held academic positions.

Other findings of this evaluation show that most of the graduates currently working in research are employed in medical schools or hospitals and have appointments to clinical departments. In addition, seven graduates have research staff positions at the National Institutes of Health. A majority of the 56 "research" graduates indicate they are doing basic research, but the distinction between fundamental and clinical research was not clearly defined. Most graduates in academic settings are now assistant professors, but about 30 percent are ranked associate professor or professor. There is no single complete measure of a successful research career, but two reasonable indicators are a scientist's research publications in reputable journals and his or her research grant support. From the literature searches, it was found that the "research" graduates have a mean of 21 research publications, with a median of 11. Of these 56 graduates, 9 receive internal research support through Federal employment at either the NIH or at the Uniformed Services University of Health Sciences; 27 serve as principal investigators on a total of 37 NIH and/or NSF research grants, and 20 have no independent NIH or NSF research support.

Recommendations

The program appears to be accomplishing the goals set for it. The NIGMS senior leadership believes that this program is of an appropriate size and should continue to be supported at the current level, provided its high quality is maintained. In the opinion of NIGMS senior staff no new directions for the MSTP program are indicated by the study.

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

Evaluation of Recruiting Efforts in Clinical Pharmacology Programs

Definition and Description of Program

The Pharmacological Sciences (PS) Program of the National Institute of General Medical Sciences (NIGMS) supports all aspects of pharmacology-related research for synthesis and development of pharmacologically active chemical structures, through elucidation of their mechanisms and sites of action to improving the clinical use of drugs. Most of the research funded by the program is in the form of research grants.

In addition to multidisciplinary predoctoral training programs in PS, the program also includes an institutional and individual postdoctoral training program, which emphasizes research training in clinical pharmacology. Individuals receive experience in the methodology and conduct of clinical research to qualify them to investigate the effects and the mechanisms of drug actions in humans. Trainees usually hold the M.D. degree. Concern has been expressed at NIH about the sharp, continuous decline in the number of M.D.'s choosing research-oriented careers. Because M.D.'s should be well qualified for biomedical research and better qualified than anyone else for clinical research, this is perceived as a real and serious problem. The NIGMS Council has had ongoing discussions of the difficulties facing M.D. graduates and the economics of clinical practice versus an academic research career. Each program has its own concerns regarding the challenge of recruiting efforts for post-M.D.'s into appropriate careers.

Evaluation Study Performed

Design of Study

The program supported 14 Institutional National Research Service Awards in clinical pharmacology during FY '80. The total support for this program was close to $1 million. During FY '80, approximately 45 postdoctoral trainees were supported on these 14 training grants.

The Pharmacological Sciences Program organized two workshops under this evaluation. The first consisted of program directors of these Clinical Pharmacology training grants, and the second comprised senior trainees from the Clinical Pharmacology Programs supported by NIGMS as well as selected

trainees from the NIGMS Anesthesiology Postdoctoral Training Programs. Among the topics discussed at both workshops was the problem of recruiting appropriate post-M.D. trainees for these training grants. Another issue that was examined, particularly by the program directors' workshop, was the advisability of limiting or strongly encouraging the appointment of only post-M.D. trainees to these training slots. Another idea that derived from this workshop was the possibility of the Clinical Pharmacology Programs sharing the availability of suitable trainees when one program no longer had slots available for appointment of new trainees.

Recommendations

Specific recommendations included the above-mentioned sharing of the availability of appropriate trainees among the different program directors as well as the advice that NIGMS strongly urge the programs to reserve their slots for suitable post-M.D. trainees. It was also suggested that the NIGMS not make a unilateral policy decision to limit approval for appointment of only post-M.D. trainees. The feeling was that the program directors themselves should be entrusted with the decision as to what makes the most appropriate clinical pharmacology trainee.

Implementation

Implementation of the results of these workshop activities will take place during the next two fiscal years, when practically all 14 clinical pharmacology training programs will be up for competitive renewal. The reviewers will be able to use the recommendations in evaluating the currently funded programs as well as the potential of a few newly organized programs. Funding recommendations to the Director, NIGMS, will be made with the background of the long discussions held at the workshops.

In addition, a joint committee of The American Society for Clinical Pharmacology and Therapeutics and The American Society for Experimental Pharmacology and Therapeutics is using the statistical data in its recommendations regarding future activities in training in clinical pharmacology and in its discussions of instituting formal board examinations in clinical pharmacology.

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

Evaluation of the NIH Research Center Awardees
(Recipients of K06 Awards)

Background and Description

Members of the biomedical research community have recently expressed interest in having a funding mechanism to provide long-term salary support for investigators of established merit. From 1961 to 1964, NIH had a Research Career Award Program (K06) that encompassed similar aims. This program provided essentially lifetime support to qualified, experienced investigators to continue in careers of independent research. The intent was to provide these awardees with financial stability that was not dependent solely on renewal of research grants every 3 to 5 years. The awards were based on the candidate's training, experience, and accomplishments and were limited to $25,000 per year plus indirect costs. An awardee could not transfer the award from one institution to another.

In 1964, a decision was made by NIH not to make new K06 awards. During the course of the program, the NIH made 236 career awards. The average length of an award has been 11.6 years. In 1980, 76 awardees were still being funded.

The decision to discontinue the program was based upon documented fiscal and programmatic considerations.* Considering the interest of some members of the scientific community in reestablishing such a program, it is appropriate to evaluate the performance of the individuals who received K06 awards. By comparing this performance to that of contemporaries without benefit of this support, it should be possible to determine whether the expenditure of these funds yielded a result that could not have been gained without this support.

Evaluation Study Performed

Description of Study Design

Scientific productivity and the quality of research endeavors were used as criteria for measuring the achievements of the K06 recipients after receiving the award. Scientific productivity was measured by the number of publications of each investigator. These data were obtained from computer MEDLINE searches; each citation was checked to determine that the cited

*Background of Decision to Discontinue Career (K06) Awards, Office of the Director, National Institutes of Health, June 1965.

author was the investigator who had received the K06 award, and to eliminate abstracts or citations not related directly to the investigator's scientific activities.

The quality of a senior investigator's research was evaluated by analysis of the priority scores given by initial peer review groups of the individual research project or program project grant applications submitted by the investigator. The average of the priority scores obtained on all research grant applications submitted to NIH was used as a criterion of the evaluation of an investigator's research, as judged by peers.

Data about the K06 recipients (Group A) were compared with two other groups: K06 applicants who were approved but not funded (Group B), and investigators who did not apply for K06 awards, but submitted R01 applications during 1961-1965 (Group C).

One hundred names were chosen from an alphabetical list of 300 applicants from Group B by selecting every third name on the list. For Group C, two computer-generated alphabetical lists were obtained of R01 applicants in the period 1961-1965: one with priority scores between 100-149 (C-1) and one with priority scores between 150-199 (C-2). Only those applications with randomly assigned application numbers ending in 6 were generated. All K06 awardees were deleted from this list. By selecting every third name, 50 investigators were chosen from each priority score group. Members of all groups were equivalent with respect to average age in 1966. Each group encompasses similar areas of research interests. It should be noted that, by evaluating only the number of publications, this study does not take into account the prestige of the journal or the impact on the field of the articles published. An investigator was not included in the averaged figures unless at least one publication was found in the bibliometric search.

Results of Data Analyses

Members of Group A had an average of 42.5 publications per individual between 1965 and 1979, or 3.0 publications/year. The average number of publications between 1965 and 1979 for Group B is 33.0, or 2.3 publications/year. Those in Group C-1 averaged 41.3 publications between 1965 and 1979, or 3.0 publications/year. Those in Group C-2 averaged 24.2 publications between 1965 and 1979, or 1.7 publications/year. Among the three groups the average number of publications was similar each year, with only a slight decline in later years. Members of Group C-2 had fewer publications each year after 1971. This decline was due to a marked decrease in publications by a certain segment of the group rather than a general decline.

Over the years since 1964, the average priority score obtained on research grant applications by members of Group A was 201, with all the awardees having averages better than 300. The average for members of Group B was 249. Eighty-three percent of their applications had an average priority score below 300. The average for persons in Group C-1 was 169--significantly better than the K06 awardees; moreover, 83 percent of all members of Group C-1 had average priority scores below 200, and all had averages less than 260.

Findings of the Study

It appears that this award mechanism has provided support for a group of meritorious scientists. These scientists, however, did not perform significantly better than their contemporaries who either did not apply for or did not receive a K06 award. In terms of publications, over 25 percent of Group A performed below the average performance of Group C, and only half had more than the average number of publications of the unfunded K06 applicant group (Group B). While the priority scores of the K06 awardees were better than those of the unfunded K06 applicants, they were significantly poorer than those of the C-1 group.

Furthermore, the individuals who are still receiving support from the program tend to be those who are no longer funded by research grants and who publish at a rate below that of their peers. This may be due to a restriction imposed by the K06 program that prohibits transfer of the award between institutions. This may retain in the program individuals of lower productivity, who may not have been offered opportunities to advance at other institutions.

In conclusion, long-term salary stabilization did not improve the scientific performance of its beneficiaries beyond what would have been forthcoming without this program. The data in this study do not support a recommendation to reinstate this program or one of a similar nature.

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NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

Dr. Murray Goldstein, Acting Director

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Proposed Budget

		Dollars in Thousands FY 81	FY 82	FY 83
NINCDS 77-1	The National Hospital Survey of Disease	--	--	--
NINCDS 79-301	Evaluation of Intramural Research Program	77	--	--
NINCDS 80-302	Evaluation of MEDLARS Services for Meeting the Information Transfer Needs in Communicative Disorders	240	110	--
NINCDS 82-301	Evaluation of the Scientific Impact of Research Center/Program Project Support and Individual Investigator Support in the Communicative Disorders Field	--	60	150
	Total FY 82 Set-aside Fund Request		$170	

Policy Overview

Introduction and Program Structure

The National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) is responsible for conducting, sponsoring, and guiding research into the causes, prevention, diagnosis, and treatment of over 600 neurological and communicative disorders. It provides grants-in-aid and contracts to public and private institutions and to individuals who pursue these research interests. The NINCDS also stimulates the recruitment and training of individuals to conduct research in the neurological and communicative fields. It conducts a vigorous and diverse intramural research program at the NIH and in NIH-sponsored clinics and laboratories elsewhere. Finally, the NINCDS actively collects and disseminates information to the general public as well as the biomedical community.

The NINCDS operates four major subdivisions. The programs and their major foci are:

- Communicative Disorders Program:

  Disorders of hearing, vestibular system, speech, language, effects of noise, and other special senses

- Neurological Disorders Program:

  Disorders of early life, disorders of aging including dementia, epilepsy, demyelinating sclerosing and infectious disorders, neural aspects of behavior and learning, pain, and neuromuscular disorders

- Stroke and Trauma Program:

  Cerebrovascular disorders, nervous system trauma, neuronal regeneration, and tumors of the nervous system

- Fundamental Neurosciences Program:

  Basic neurosciences and neuroprostheses.

Moreover, the Institute conducts an extremely ambitious intramural research program as well as a research training program.

Because of the number and severity of the disorders NINCDS addresses and the rapidly expanding knowledge base in these areas, it is critical that research priorities and strategies be carefully chosen. A wide range of evaluation activities helps NINCDS staff focus and monitor their plans and strategies. These evaluation activities are discussed in this FY 1982 evaluation plan for the Institute.

Role of Evaluation in NINCDS

Evaluation is an integral part of the NINCDS, and is, therefore, implicit in all phases of Institute activity. Evaluation occurs when Institute goals and plans are determined and appraised, when the impacts of the strategies designed to achieve those goals are measured, or when the efficiency or effectiveness of the strategies are judged. Formal and informal evaluation activities tie planning to administration and influence the selection of research to be supported by the Institute.

Some evaluations conducted by NINCDS use Departmental 1 percent set-aside funds. These projects are generally separate self-contained projects, with definite start and completion dates, and are often performed under contract. These formal evalution projects represent only a small part of the evaluation activities NINCDS conducts. Other activities tend to combine evaluation with planning, administration, or budgeting. It is not always easy to separate the evaluation component from these other aspects; one feeds into the other.

Evaluation results are actively used in Institute planning and management decisions. Two examples of recent projects illustrate the contribution of evaluations.

- National Research Plan. The National Research Strategy for Neurological and Communicative Disorders, published in 1980, sets out the priority goals for the Institute. This document, developed with the advice of many scientists and other experts inside and beyond the NIH, has become a touchstone by which the Institute's progress is assessed.

- External Review of Antiepileptic Drug Development Program. The Institute is currently conducting an internal program performance review and summary of the antiepileptic drug development program in concert with an external review by independent, nationally known scientists. The external review, to be held early in 1982, will augment the internal one. Together, the reviews will add and should help enhance this important NINCDS program.

NINCDS Evaluation Framework

A conceptual framework is helpful in highlighting evaluation activities. NINCDS evaluation efforts can be described along two dimensions: 1) by the major Institute function the evaluation supports, and 2) by the primary actors involved in the evaluation. Each dimension is described below:

A. Institute Function

The major functions of the NINCDS can be summarized as:

- Knowledge development
- Knowledge validation
- Knowledge dissemination and transfer, and
- Institute management.

B. Major Participants

Advisory Council

The NINCDS National Advisory Council consists of nationally recognized experts in basic and applied research in neurology and related concerns and leaders in community affairs. Mandated by Congress, this Council advises on program balance, relevance, and priorities. Council members weigh the ongoing activities of the research programs with the state of the art of knowledge development in the neurosciences. The Council also makes final recommendations on extramural research projects and their relative priorities.

Advisory Committees

Advisory committees serving each extramural program and the intramural research program provide a further review mechanism for all research sponsored or conducted by the Institute. The Board of Scientific Counselors reviews research conducted in the intramural clinics and laboratories. The separate advisory committee that serves each program helps assess the program's activities and overall performance and guide future activities in conformance to the National Research Strategy.

Internal Institute Management

At the program level and in the office of the NINCDS Director evaluation activities also occur. The development and frequent reassessment of the National Research Strategy for Neurological and Communicative Disorders has been directed and coordinated by the Institute Director. Program performance summaries are prepared by program managers to assess specific program components, their operation and impacts. At the present time two program performance summaries, one on the antiepileptic drug development program, the other on the speech program, are being completed. These should help Institute managers assess the accomplishments and impact of these two program areas.

The chart shown in Exhibit 1 illustrates how past, present, and proposed projects contribute to accomplishing the major functions of the NINCDS and shows the major participants in each.

Highlights of Previous Evaluation Efforts

Prominent examples of recent evaluation activities conducted by the NINCDS are described below.

EXHIBIT I - HIGHLIGHTS OF NINCDS EVALUATION PROJECTS BY INSTITUTE FUNCTION AND MAJOR PARTICIPANTS

EVALUATION ACTIVITY OR PROJECT	INSTITUTE FUNCTION: KNOWLEDGE DEVELOPMENT	KNOWLEDGE VALIDATION	KNOWLEDGE DISSEMINATION	INSTITUTE MANAGEMENT	MAJOR PARTICIPANTS OR COORDINATORS
Survey of Intracranial Neoplasms (NINCDS 74-1a)	X		X		NINCDS-Office of Director-Office of Biometry and Field Studies
Nationwide Survey of Stroke (NINCDS 74-1b)	X	X	X		NINCDS-Office of Director-Office of Biometry and Field Studies
National Hospital Survey of Disease (NINCDS 77-1)	X			X	NINCDS-Office of Director-Office of Biometry and Field Studies
Development of Methods for Collections of Supplementary Survey Data for Determining Trends (NINCDS 77-3)	X		X	X	NINCDS-Office of Director-Office of Biometry and Field Studies
Evaluation of Intramural Research Program (NINCDS 79-301)	X	X	X	X	NINCDS-Intramural Research Program
Evaluation of MEDLARS Services for Meeting the Information Needs in Communicative Disorders (NINCDS 80-302)			X	X	NINCDS-Communicative Disorders Program
Development of the Program Information System (PINS)				X	NINCDS-Office of Director and all Programs
Evaluation of the Scientific Impact of Research Support to Centers and Individuals in Communicative Disorders (NINCDS 82-301)	X			X	NINCDS-Communicative Disorders Program
RELATED ACTIVITIES					
Consensus Development Conferences					Scientists in and outside of NIH
1. Reye's Syndrome	X	X	X		
2. Febrile Seizures	X	X	X		
Development of National Research Strategy	X	X	X	X	NINCDS-Office of Director and scientists in and outside of NIH

NINCDS 74-1a-Survey of Incidence, Prevalence, and Cost of Intracranial Neoplasms

This survey was designed to develop a methodology to measure the incidence, prevalence, and economic costs of intracranial neoplasm. The survey was based on data collected from patient discharge records from a sample of short-term general hospitals in the coterminous U.S. The analysis of the survey data has been completed and a major article on the incidence of intracranial neoplasms has been prepared for publication.

NINCDS 74-1b-Nationwide Study of Stroke

This national survey of hospital records of patients from short-term general hospitals was designed to provide: 1) reliable national estimates of the incidence of acute hospitalized stroke by age and sex; 2) survival data and estimates of prevalence among persons with a history of hospitalized stroke; 3) the economic impact of stroke on the patient and society; and 4) data on the related clinical aspects of stroke. The study has now been completed and the results published in a brochure as well as in a monograph entitled The National Survey of Stroke (March/April 1981).

NINCDS 77-1-The National Hospital Survey of Disease

The purpose of this study was to develop a methodology to test the feasibility of a data collection system for obtaining incidence and prevalence data from a national sample of hospital discharge records for selected neurological and other diseases. The feasibility study has been completed and analysis is now being conducted. A report of the analysis is expected to be completed in the fall of 1981.

NINCDS 77-3-Development and Test of Methods for Collection of Supplementary Survey Data for Determining Trends. Phase IV of the Head and Spinal Cord Injury Survey.

This study was undertaken to develop the capability of producing periodic estimates of incidence, prevalence, and health costs for selected neurological disorders. A national survey of head and spinal cord injuries was conducted to determine the magnitude of the problem of these types of injuries in the United States. The study, using a sample of hospital records, addressed the onset, duration, and termination of injury, resulting morbidity, and economic costs. "Report on the National Head and Spinal Cord Injury Survey" was published as a supplement to the Journal of Neurosurgery in November 1980.

Current and Proposed Projects

NINCDS 79-301-Evaluation of Intramural Research Program

The Intramural Research Program of NINCDS seeks to develop and use methods of citation analysis (bibliometrics) to evaluate, through objective measures, the influence of its laboratories and scientists

on the bioscience communities at large. A 12-month contract was awarded on January 12, 1981. Tabulations of citation data and syntheses of findings are expected in the fall of 1981.

NINCDS 80-302-Evaluation of MEDLARS Service for Meeting the Information Transfer Needs in Communicative Disorders

The purpose of this study is to determine whether MEDLINE services meet the information needs of specialists in communicative sciences, including clinicians and researchers, and whether these specialists can learn to use MEDLINE independently without the help of technical information specialists. Five information centers have been set up in the U.S.A. and 500 potential users have registered to participate in the study. Data on current information needs are being analyzed. After the training workshops, users will have access to MEDLINE services. A profile of MEDLINE utilization will be analyzed by Summer 1982.

NINCDS 76-1-Development of the Program Information System (PINS)

The NINCDS is implementing a major management and evaluation tool in its automated Program Information System (PINS). This system has been developed with NINCDS operating funds as well as with evaluation set-aside funds (contract no. NO1-NS-6-2345). It is expected to begin operating in the fall of 1981. PINS is an integrated data base management system, the first of this type at the NIH. The PINS System will allow Institute scientists and managers to obtain information rapidly on research grants, contracts and intramural projects, budget, operating expenditures, planning, and Institute personnel. PINS will contribute to many Institute planning and evaluation activities. For example, its expanded classification system for research supported by the Institute will improve our capability to monitor and evaluate the research thrusts of each program area.

NINCDS 82-301-Evaluation of the Scientific Impact of Research Center/Program Project Support and Individual Investigator Support in the Communicative Disorders Field

NINCDS proposes to use FY 1982 evaluation funds to conduct this study. The study will attempt to determine the relative merits of different research support mechanisms for furthering clinical and basic research in the different otolaryngological, vestibular, hearing, speech, and language fields. The information produced for this project should help the Institute fine-tune its grant priorities and procedures. Because of Institute personnel limitations, this project would be conducted by an outside contractor. It would begin in FY 1982 and, under the current schedule, be completed by July 1984. This project has been reviewed and approved by the NINCDS Acting Director and by the Ad Hoc Advisors to the Communicative Disorders Program.

Conclusion

Evaluation plays a key role in NINCDS management and resource allocation decisions. The commitment to analyze program impacts has increased as has the determination to use evaluation results in managing the Institute and planning its activities. As the PINS system becomes fully operational, the Institute's ability to conduct a wider range of ad hoc and longer term evaluation activities will increase. Moreover, the tying of internal and external or independent program performance reviews, as in the antiepileptic drug development program, should increase the Institute's evaluation skills and knowledge as well as provide valuable information about an important program.

NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

Evaluation of the National Survey of Stroke

Definition and Description of Program

Stroke is the third leading cause of death in the United States and accounts for 10 percent of all deaths. While there are national stroke mortality statistics. far less is known about the national incidence of stroke, types of stroke, the characteristics of patients, stroke morbidity and survival, and direct and indirect costs associated with the disease. The NINCDS National Survey of Stroke was conducted to provide this information. The major goal of the survey was to collect detailed clinical and epidemiological data to serve researchers and clinicians. These data will help NIH research planners and the United States Congress in assessing research needs and setting priorities for stroke-related research.

The survey had several specific objectives, including:

- To produce national, statistically adequate data on stroke. Before the survey, epidemiological data on stroke were limited to local surveys, which could not provide adequate or comprehensive estimates of the disease on a national level.

- To obtain baseline data on stroke. Preventive and therapeutic technologies and regimens for stroke are changing rapidly. The baseline portrait will eventually allow us to determine the effects of these changes.

- To help assess results of recent Federal and nongovernmental efforts to control hypertension, a cause of stroke. The National High Blood Pressure Education Program sponsored by the Department of Health and Human Services was one such program. The stroke survey was designed to identify recent national trends in stroke, and to detect any changes in incidence.

- To improve existing knowledge of epidemiological research based on hospital records. The stroke survey, following similar NINCDS-sponsored epidemiological surveys on muscular dystrophy and head and spinal cord injury, would add to the current state of knowledge and implement methodological improvements identified in earlier studies.

Evaluation Study Performed

Design of Study

The National Survey of Stroke used a stratified random sample of hospitalized cases of stroke in the United States. It included patients hospitalized in the years 1971, 1973, 1975, and 1976. The individual hospital record was the major source of data for all patients. For a subset of strokes, data were also collected from the physician and the patient or patient's family. A detailed clinical description or algorithm was developed to identify and type strokes and was then applied to the medical records. Extensive analyses of the data addressed such factors as sex and age differences, survival expectations, therapeutic and diagnostic procedures, and prior health status. In addition, a cost analysis estimated direct and indirect costs to the patient and to society of a stroke requiring hospitalization.

Results of Data Analyses

The National Survey of Stroke contributed greatly to our knowledge of stroke. Among its findings were the following:

- There were 137.9 initial strokes per 100,000 persons and 91.3 stroke deaths per 100,000 persons in 1976.
- Both stroke deaths and initial strokes declined between 1971 and 1976. The stroke death rate declined 12.5 percent during that time, and age-adjusted mortality from stroke declined 50 percent between 1950 and 1978.
- Adjusting for age, men have 44 percent more strokes than women. Men have far more thrombotic and embolic infarctions than do women.
- Stroke is a disease of the elderly. For example, 46.1 percent of stroke patients are 75 years of age or older, although they constitute only 4.3 percent of the United States population.
- The probability of survival status varies with the type of stroke and certain clinical signs. For example, patients with hemorrhagic strokes are less likely to survive 30 days than are those with other types of strokes.
- Hypertension, heart disease, and previous stroke are related to incidence of stroke. The effect of each medical condition varies by the type of stroke.
- The annual cost of stroke was $7.4 billion in 1976. Of the total, $4.1 billion accounted for the indirect costs of loss of earnings, while direct health care costs approached $3.3 billion.

The survey report also made numerous recommendations about the technical aspects of the survey, including use and limitations of hospital records, follow-up approaches, imputation of missing data, sampling, hospital enlistment, and timing of future surveys.

Implementation

The survey was very successful. First, it produced a statistically valid baseline of the national experience with stroke. This information has been widely disseminated to the medical community and the public. The survey and its findings have been cited in Congressional testimony and reports to the Congress. The results are now being used as a basis of comparison in local studies. Furthermore, anecdotal evidence suggests that the study findings, the clinical algorithm for identifying and typing stroke, survival probabilities, and other information are very helpful in clinical practice. Second, the survey data seem to provide further information on the effectiveness of the national campaign to control hypertension. The incidence of stroke was clearly shown to have decreased during and after the campaign. Thus, the survey results are consistent with current attempts at NIH and elsewhere to identify and control high blood pressure. Third, the National Survey of Stroke and its results have contributed to the methods of epidemiological and policy research. The cost-finding approach used in the study has been used widely, and the analysis of the costs of stroke has served as an example of the approach in DHHS and elsewhere. Both the results and the methodologies of the survey have contributed to the design of the National Stroke Data Base, a very detailed patient file being compiled by the NINCDS for research. Finally, the survey results demonstrate the importance of the timing of an epidemiological study to coincide with changes in medical technologies. A survey recommendation was to delay further national epidemiological surveys of stroke until the preventive and therapeutic technologies now being introduced are widely used. Timing a survey in this way will allow the results of the technologies to be measured, as well as changes in the national stroke incidence.

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DIVISION OF RESEARCH RESOURCES

Dr. James F. O'Donnell, Acting Director

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Proposed Budget

		Dollars in Thousands FY 81	FY 82	FY 83
DRR 82-301	Short-Term Evaluations of the Programs of the Division of Research Resources	--	300	--
	Total Set-Aside Fund Request		$300	

Policy Overview

The Division of Research Resources (DRR) develops and supports a wide variety of multicategorical, interdisciplinary research resources which are essential to biomedical research. These resources are used by a broad spectrum of investigators to enhance their own effectiveness and that of their institutions in responding to and carrying out the mission of the National Institutes of Health. They include Biotechnology Resources, which provide access to the latest technologies from the physical sciences, mathematics, and engineering for biomedical investigators; General Clinical Research Centers, which are specialized research units within larger hospitals which provide research beds and accompanying professional support services necessary for the conduct of clinical research; and Animal Resources, which support projects that result in the most effective use of laboratory animals in health-related research, in addition to supporting the seven national Primate Research Centers and a number of animal colonies of unusual and special value for research. The Division also awards Minority Biomedical Support Grants to increase the participation of ethnic minority students and faculty in the biomedical sciences and health professions; and Biomedical Research Support Grants to enhance the effectiveness and efficiency of biomedical and behavioral research at institutions receiving PHS grant support, by providing them with funds for use as they choose for activities such as, but not limited to, pilot research projects, shared research equipment, centralized research services, and start-up costs for young investigators.

The Division has long been committed to examining program performance and impact through evaluation activities that are coordinated with planning on both the individual program and Division levels -- including studies that describe or measure the effects of program operation, and that identify needs for research resource programs. The costs -- both dollars and time -- of such studies are included in the overall allocation of Division resources.

DRR's planning and evaluation activities are mutually supportive. For example, in preparing the Division's Five-Year Plan, attention was called to needed evaluations, and all of the Division's program goals and objectives were specified and further clarified by setting out research opportunities and initiatives. These objectives are now being restated by DRR staff in a form most useful for evaluation. (The DRR Five-Year Plan, 1982-1987, was distributed to the scientific community in December 1980, and responses are currently being reviewed by the Division's planning staff and management.)

FY 82 Evaluation Strategy Statement

While the Five-Year Plan is being implemented and updated for the period 1983-1988, DRR attention is turned toward evaluation: One of the major priorities of all program staff through early Fiscal Year 1982 will be laying the groundwork for a coordinated evaluation process addressing all of the Division's programs. This activity is planned in four phases:

Agreed-upon objectives and indicators (phase one)
During the period March through June 1981, the objectives of all DRR programs and major subprograms are being set out in as measurable terms as possible. Indicators are being developed for the objectives, and the finished packages will be distributed through OD, NIH, after concurrence by the Acting Director, DRR.

Program performance summaries (phase two)
Between July and October 1981, program performance summaries will be developed for all programs using the phase one agreed-upon objectives and indicators as the starting points.

Short-term evaluations (phase three)
Building on the program performance summaries, short-term evaluations will be performed for all of the Division's programs and major subprograms between November 1981 and April 1982. The program performance summaries developed during phase two will be enlarged during this phase to include phase three results.

Decision-making for FY 1983 Evaluation Plan (phase four)
Taking into account the program performance information available in the summary, and resulting from the short-term evaluation of each program, DRR staff will decide on the need for further evaluations (full-scale, long-term) of the Division's programs. This process will be facilitated by the evaluation methodology developed for each program as part of its short-term evaluation during phase three.

Major Projects Recently Completed

Two evaluation studies for the Animal Resources Program have been recently completed and are contributing to DRR program planning. The Primate Research Centers Evaluation Study (DRR 77-1) Final Report was issued in January 1979. This study concluded that the Primate Research Centers Program had served the advancement of science, medicine, and primate biology, but that certain changes were needed to assure maximum effectiveness in the future. Seven of the 12 recommendations made by the evaluation panel were provided for during development of the Five-Year Plan mentioned above. The second study, A Survey of Laboratory Animal Facilities and Resources Supporting Biomedical Research (DRR 77-5), was completed in March 1980. While containing no recommendations per se, this extensive survey is proving to be quite useful in planning for the Program's activities, as it detailed unfilled needs and future requirements for research animals, animal resource personnel, facilities, and programs throughout the United States.

The third recently completed study was carried out for the General Clinical Research Centers Program (GCRCP). The GCRCP seeks to establish and make available to medical scientists the resources necessary for the conduct of high-quality clinical research studies. The Centers are intended to provide as optimal an environment as possible, including all the latest supporting systems and technical tools which researchers need. The study, Evaluation of the Role of Clinical Research Centers in

Clinical Trials, With Emphasis on Information Processing (DRR 77-2), was completed in November 1980. The first phase of this study was completed with the preparation, in December 1979, of an interim report characterizing clinical trials supported by NIH, both within the GCRCs and by the other Institutes. The study then went on to examine the organizational, administrative, operational, and information-processing needs of the clinical trials carried out on and between the GCRCs to determine whether the Centers are providing an optimal environment for these trials. The final versions of both the interim and final reports were received by the Division in April 1981. The findings and recommendations of the study are being reviewed by the program and will be included in future planning.

New Projects Proposed

In Fiscal Year 1982, the Division proposes to contract for Short-Term Evaluations of the Programs of the Division of Research Resources (DRR 82-301). These evaluations will produce, for every program and major subprogram, (1) summaries of available and readily obtainable data on program performance in terms of objectives and indicators; and (2) alternative approaches to acquiring more program performance data through the use of long-term/full-scale evaluations -- specifying the additional information that would be produced and the costs of producing it. The preliminary estimate for this project is $300,000 in Fiscal Year 1982.

DIVISION OF RESEARCH RESOURCES

Evaluation of the Scientific Mission of DRR

Definition and Description of Program

The Division of Research Resources (DRR) develops and supports a wide variety of multicategorical, interdisciplinary research resources that are essential to biomedical research. These resources are used by a broad spectrum of investigators to enhance their own effectiveness and that of their institutions in responding to and carrying out the mission of the National Institutes of Health. The Division's FY 1982 President's Budget request was $191.863 million.

Evaluation Study Performed

Design of Study

In 1975 a major evaluation of the scientific mission of the Division of Research Resources was undertaken. It included a systematic assessment of the scientific mission, goals, and performance of the DRR and its constituent programs, encompassing both the quality of the DRR programs themselves and their impacts on the other programs of the NIH and on the Nation's biomedical research community.

The study was carried out by a panel of national leaders from both the scientific and lay communities, supported by an additional group of technical consultants. The primary mechanism of data collection used by this panel was the conduct of structured "resource interviews" at the sites of projects, including resources not supported by DRR, as well as analysis of data obtained from NIH grant and contract records. In addition, interviews were carried out with NIH Institute Directors; the Director, NIH; Council and advisory committee members; the Office of Management and Budget; former Directors of NIH and former staff of DRR; the Office of the Assistant Secretary for Health, DHEW; and staff of the Division of Research Grants and members of various study sections.

The findings and recommendations were presented to the management of DRR in October 1976. The Division identified factual errors contained in this report, and the final report was made available to the Director, NIH, in

November 1976. In March 1977, as previously agreed to by the Director, NIH, the results of the review of the study by DRR initial review groups and the National Advisory Research Resources Council were forwarded to the Director, NIH, while the Division began using them as the basis of its five-year plan completed in 1980.

Recommendations Resulting From Study

- The panel strongly urged an expanded role for the Division (including designation as a National Institute) in the overall management and coordination of research resources throughout the NIH--an issue currently receiving attention as part of an NIH-wide examination of its research resource-related programs, and the discussion of a "national research resources program."

Administration Action Items

- DRR should request expansion of the membership of the National Advisory Research Resources Council from 14 to 20 (12 scientific, 6 lay, plus 2 ex officio); charter and establish appropriate Council subcommittees; and develop a more formal Council-to-Council liaison process.

- The Director, NIH, should allocate and increase the number of permanent full-time positions to DRR.

Animal Resources

- DRR should conduct an outside, in-depth review of the entire Primate Research Center, Primate Resources, and Primate Research Service Programs.

- DRR should work to make the Primate Research Centers a more integral part of their "host" institutions.

- DRR should place increased emphasis on development of new animal models; preservation of genetically defined animal stocks; and primate breeding activities.

- DRR should place increased emphasis on training programs in laboratory animal medicine, pathology, and related sciences in order to expand the highly productive diagnostic laboratory program.

- DRR should place increased emphasis on extramural animal resource improvement activities, both administratively and financially.

Biotechnology Resources

- DRR should preserve and enhance the innovative role that biotechnology resources play in the evolution of biomedical research.

- DRR should work with and fund developing technologies at the pre-resource level in order to develop their resource capabilities.

- DRR should expand its research support on the backup data management technologies needed in large-scale clinical trials.

General Clinical Research Centers

- DRR should increase inter-Center and intra-NIH communication regarding clinical research "center" activities and opportunities.

- DRR should characterize and develop appropriate and needed resources to improve the clinical trials capabilities of the General Clinical Research Centers.

- DRR should continue development and distribution (in conjunction with the Biotechnology Resources Program) of software/hardware ensembles that can best serve clinical research.

- DRR should increase its visible programming for General Clinical Research Centers to assure greater and more open competition.

Minority Biomedical Support

- DRR should request and appropriately use prebaccalaureate, predoctoral, and postdoctoral training authority for the Minority Biomedical Support Program.

- DRR should request authority and additional funds for indirect costs for the Minority Biomedical Support Program.

- DRR should allocate increased permanent full-time staff for the Minority Biomedical Support Program.

Biomedical Research Support

- The Director, NIH, should make every effort to assure the continuation and stability of the Biomedical Research Support Grant Program.

- DRR should develop, execute, and widely distribute the findings of a cost/value analysis of the program.

Organization Response to Recommendations

Administration Action Items

- The Council was expanded in 1977, followed by the establishment of a Council subcommittee for each of DRR's five programs, as well as a planning subcommittee. A Council-to-Council liaison process was begun at that time and continues to expand.

- Budgeted positions have increased from 75 in FY 1975 to 79 in FY 1981.

Animal Resources

- A Primate Research Centers Evaluation Study was completed in 1979.
- Recommendations contained in the study mentioned above are being used by the staff of the program in an attempt to modify the attitudes of some of the institutions where Primate Research Centers are located.
- Initiatives in the areas of new animal model development, preservation of genetically defined animal stocks, and primate breeding activities have been proposed as part of the long-term plan of the Division.
- Training continues to receive a high priority in the Division's long-term planning activities.
- A national survey was conducted to determine the extent of the need for this type of support. The results have been disseminated to the management of NIH and are being included in the Division's five-year planning activities. Availability of funds in this area continues to be a high-priority recommendation of the Division in its planning activities.

Biotechnology Resources

- This program has the highest priority focus in DRR's Five-Year Plan and annual research plans.
- Preresource grants have been made a part of the program.
- An initiative in backup data management technology has been proposed as part of the Division's Five-Year Plan.

General Clinical Research Centers

- Inter-Center and intra-NIH communication regarding the Centers' activities has been stepped up as part of an overall communication effort that includes directories of all DRR grantees and resources--including their capabilities and services--and publication of a widely distributed newsletter, the Research Reporter.
- A study, "Evaluation of the Role of Clinical Research Centers in Clinical Trials, With Emphasis on Information Handling," has been completed. Study recommendations for additional resources to improve the clinical trials capabilities of the General Clinical Research Centers are currently being studied.
- The development and distribution of software/hardware ensembles continues (in conjunction with the Biotechnology Resources Program),

with the dissemination of a specialized computer system (CLINFO), developed by both programs working together, and the consideration of the evaluation study cited above.

- Visible programming for the General Clinical Research Centers has been accomplished as part of the larger communications effort.

Minority Biomedical Support

- Prebaccalaureate, predoctoral, and postdoctoral training authority for the program has been requested; indirect costs are being awarded to grantees; and the permanent full-time staff for the program has been augmented.

Biomedical Research Support

- The Director, NIH, has consistently supported the continuation and enhancement of the program.

- This program will be evaluated with the others, as part of an overall evaluation of the Division's programs.

Recommendations and Results

The panel strongly urged an expanded role for the Division (including designation as a National Institute) in the overall management and coordination of research resources throughout the NIH--an issue currently receiving attention as part of an NIH-wide examination of its research resource-related programs, and the discussion of a "national research resources program."

References

Assuring the Resources for Biomedical Research: An Evalution of the Scientific Mission of the Division of Research Resources, NIH, Bolt, Beranek, and Newman, Inc., (BB&N Report No. 3445), 1976, EDC 0899.

Preliminary Response to the Report of the Research Resources Evaluation Panel: "Assuring the Resources for Biomedical Research," Division of Research Resources, NIH, January 1977.

DRR Executive Summary of the Report of the Research Resources Evaluation Panel: "Assuring the Resources for Biomedical Research," Division of Research Resources, NIH, March 1977.

Response to the Report of the Research Resources Evaluation Panel: "Assuring the Resources for Biomedical Research," Division of Research Resources, NIH, November 1977.

Status Report on Actions Taken by DRR Regarding Recommendatons of the Research Resources Evaluation Panel Report (BB&N Study) as Set Forth in DRR's Executive Summary, dated March 21, 1977, Division of Research Resources, NIH, June 1978.

Division of Research Resources 1982-1986 Five-Year Program Plan, NIH, October 1980.

Primate Research Centers Evaluation Study, JRB Associates, Inc., 1979, EDC 1505.

National Survey of Laboratory Animal Facilities and Resources, FY 1978, Committee on Laboratory Animal Resources and Facilities, Institute of Laboratory Animal Resources, National Academy of Sciences, 1980, EDC 1506.

The Role of General Clinical Research Centers in Clinical Trials: A Characterization With Recommendations, The RAND Corporation, 1980.

A First-Order Characterization of Clinical Trials, The RAND Corporation, 1980.

National Primate Plan, Interagency Primate Steering Committee, DHEW Publication No. (NIH) 80-1520, 1978.

DIVISION OF RESEARCH RESOURCES

Evaluation of Primate Research Centers Program

Definition and Description of Program

The Primate Research Centers Program was initiated in 1961. Within a period of five years, a network of seven centers was established. Distributed throughout the United States, these centers provide specialized resources (physical facilities, technology, professional and technical staffing, a variety of primate species, etc.) necessary for primate-based research studies of human health problems. In addition to breeding most of the animals they need, the centers share their knowledge throughout the world for use in laboratories, as well as in the conservation of natural populations. The budget allocation for the program in FY '81 was $17.2 million.

Evaluation Study Performed

Design of Study

The purposes of this evaluation study were to provide an assessment of the current missions and activities of the Primate Research Centers; advice concerning the future directions, goals, and management of the program; and a survey of other nonhuman primate research resources with general recommendations regarding their national mission. The panel comprised nine non-Federal members selected on the basis of their scientific expertise as related to primate research, primate supply, and demand; their understanding of the general NIH biomedical research budgetary and funding process; and their individual geographic locations. The evaluation was coordinated and rendered support logistically by a contractor, without interference by NIH program staff. All reports were prepared by the panel itself, with management assistance and final editing by the contractor. The 12-month evaluation involved site visits to each center and host institution; review of pertinent current and historical documents and previous reviews; and discussions with the center directors, their staffs, and the principal investigators of the centers. The specific findings and recommendations were related by the panel to the Director, Division of Research Resources, and the Director, NIH, at the conclusion of the study.

Recommendations

- The centers should be viewed as both <u>regional</u> and <u>national</u> resources.

- Primate breeding toward self-sufficiency within the program by 1985 should be encouraged in view of international problems in relation to primate supply.

- Much of the facilities and equipment of the centers is now in various stages of deterioration and obsolescence.

- The centers and their host institutions need to clearly define the responsibilities of each in areas of quality control of scientists and fiscal support.

- The program must maintain a significant commitment to creative research, and opportunities must be provided for senior investigators as well as creative young scientists to explore new paths.

- The Subcommittee on Primate Research Centers of the Animal Resources Advisory Committee should assume a more active role in the administration of the program by reviewing annual reports and regular reports from the centers.

- The current number of centers is sufficient and there is enough geographic dispersion to assure reasonable access to major groups of scientists.

- The Division of Research Resources should continue to support other primate resources. The first priority of such support would be breeding; the second, model development; then field studies, training programs, and maintenance of endangered species that have potential biomedical utility.

Implementation

- Primate breeding, both within the centers for self-sufficiency and outside the centers, was identified as a major priority of the Division of Research Resources (DRR). The centers have been encouraged to assess their future requirements for each primate species and to maintain or increase their breeding efforts to meet these needs to the maximum extent possible within the restraints of available funds.

- Detailed projections of major renovations and equipment needs at the centers have been developed and prioritized, and have been included in DRR long-term planning.

- The program guidelines have been revised to address the responsibilities of the host institutions. These guidelines are being used in discussions with the host institutions regarding their relationships with the centers and to emphasize the responsibilities of both the host institutions and NIH in the future operations of the centers.

- The centers have been authorized to budget funds for new and creative investigations. Guidelines for this type of effort have been approved by the Subcommittee on Primate Research Centers of the Animal Resources Advisory Committee and forwarded to all centers.

- Annual progress reports from the centers have been reviewed by the Subcommittee on Primate Research Centers of the Animal Resources Advisory Committee. Staff has taken action to schedule the competitive reviews of applications from the centers in a manner that will permit maximum participation by the Committee.

Reference

Primate Research Centers Evaluation Study, JRB Associates, Inc., 1979.

DIVISION OF RESEARCH RESOURCES

Evaluation of the Role of Clinical Research Centers in Clinical Trials

Definition and Description of Program

The General Clinical Research Centers Program (GCRCP) operates 75 centers in major teaching hospitals and universities throughout the United States. More than 3,000 clinical studies are pursued annually at these centers by an even larger number of clinical researchers. With a FY '81 budget of $60 million, the program supports 80 percent of the inpatient research of the NIH extramural research program. In addition, an extensive outpatient activity is conducted within the existing centers, which supported 101,216 outpatient visits in FY '80.

Evaluation Study Performed

Design of Study

The President's Biomedical Research Panel recommended that the support for GCRCs be reviewed with the intention of making this program more widely available as a proper method of supporting clinical trials. Since it seemed probable that, with increased emphasis on clinical trials, resources such as case workers, skilled outpatient research nurses, and computer-based record systems might facilitate high priority clinical trials on GCRCs, this study was intended to develop a broad understanding of clinical trials, their organizational, administrative, operational, and information processing problems, and potential solutions; describe the kinds of clinical trials currently supported by NIH and other Federal or non-Federal agencies; determine and assess whether resources now provided in GCRCs are adequate to meet the increasing needs of clinical trials; and determine whether existing methods of handling data collection and analysis for clinical trials are adequate, and if not, whether aditional computer resource development would be helpful.

The contractor visited carefully selected leaders and experts involved in the process of clinical trials, including people who are respected leaders in the conduct of clinical trials, appropriate people from the staffs of clinical trials coordinating centers, leading clinical investigators from cooperating clinics, and personnel at GCRCs involved in the performance of clinical trials.

Results of Data Analyses

By analysis of these informal interviews the contractor determined how the different types of clinical trials are designed and controlled, characterized current inpatient and outpatient resources and information systems available in GCRCs for small- and medium-sized collaborative clinical trials, characterized the present data management and analysis systems used in clinical trials, and determined the needs for these systems.

The contractor found that the GCRCs surveyed had an average of 15 active clinical trials, and that half of the resources used were used to support these trials. The typical director interviewed believed that clinical trials create problems in terms of ethics, resource allocations, and funding renewal. Most directors believed that trials could be improved if there were more outpatient facilities and computational resources were improved. Several directors saw a need for more laboratory technicians, social workers, and data collectors.

Recommendations

- Provide research data coordinators to support clinical trials.
- Make biomedical scientists (e.g., biostatisticians and computer programmer/analysts) available in the GCRCs on a regular, limited basis.
- Make the CLINFO (clinical information) data management and analysis system available to clinical trials that use GCRC resources.
- Augment the functional capabilities of the CLINFO system to include analysis of covariance, improved data editing, document tracking, sample size determination, and randomization.
- Provide a computerized nutrition data base and diet calculation program for GCRC dietitians.
- Provide fiscal management and word processing computer programs for GCRC administrative coordinators.
- Explore methods to improve the quality of clinical trials by helping investigators to improve their practice of research methodology, statistics, and information processing.

Implementation

- At the review for competitive continuation of a GCRC, special attention is paid to the request for nurses, data managers, and biostatisticians who will be involved in clinical trials.
- Efforts will be made by the GCRC branch to disseminate the CLINFO system to more GCRC sites involved in clinical trials.

- Some of the proposed additions to the CLINFO software for improving the statistical analysis of clinical trials have already been made. More changes were discussed by the CLINFO systems managers at their last meeting.

References

Report of the President's Biomedical Research Panel, DHEW Publication No. (OS) 76-500.

The Role of General Clinical Research Centers in Clinical Trials: A Characterization with Recommendations, The Rand Corporation, 1980.

A First-Order Characterization of Clinical Trials, The Rand Corporation, 1980.

DIVISION OF RESEARCH RESOURCES

National Survey of Laboratory Animal Facilities and Resources

Definition and Description of Program

The Animal Resources Program is charged with enhancing biomedical research by improving animal quality and/or availability. Animals are required in slightly over half of the research projects supported by NIH, and large experimental errors can be introduced into research projects if their quality is not carefully controlled. The program supports projects in the following areas: institutional animal resource improvement, animal resource laboratories, animal models and special colonies, resource-related research projects, and training in laboratory animal medicine. Current program activities are funded at a level of slightly over $7.0 million dollars (down from $7.8 million in FY '80). In a time of limited resources, the balance between the various ongoing activities and newly perceived needs must be carefully modulated in response to the requirements of the national research effort.

Evaluation Study Performed

Design of Study

To assist in the management of this program and to provide information for all decision-makers concerned with research involving animals, a national mail survey was commissioned. This survey collected and analyzed objective data on the current status of, unfilled needs in, and future requirements for research animals, animal resource personnel, and animal-related facilities and programs throughout the United States. Although primary attention was given to nonprofit organizations, data were also received from Federal agencies, commercial research laboratories, the pharmaceutical industry, and nonprofit organizations that use animals for other purposes than biomedical research.

Results of Data Analyses

- Animal use and sources

  -- The number of laboratory animals acquired during the last decade and available for research has decreased.

- -- The majority of respondents that acquire animals from their own breeding sources do not maintain genetic records--a substandard practice that is incompatible with quality research.

- -- There is a substantial decrease in the number of nonhuman primates available for research.

- -- Seven percent of nonprofit biomedical research organizations are importing animals from outside the continental United States.

- Facility administration and personnel

  - -- Approximately 82 percent of all responding organizations stated that they were in compliance with DHHS guidelines for care and use of laboratory animals; however, a relatively high number of organizations that were planning to apply for accreditation at the time of an earlier survey in 1968 did not, or could not, achieve that status by the time this survey was made in 1978.

  - -- Personnel changes during the last decade reflect an emphasis on quality animal care that is expected to continue at least through the next decade.

- Facilities and equipment

  - -- Approximately 16 percent of all nonprofit biomedical research organizations reported a need for replacement of some animal facility space now in use, 38 percent reported a need for remodeling to protect the integrity of space now in use, and 43 percent reported a current need for additional space. Approximately $350 million is required to meet these current needs, and another $407 million (in FY '78 dollars) will be required to meet space needs projected for FY '88.

  - -- Nonprofit biomedical research organizations reported a current need for $43 million for equipment renovation, replacement, or additions.

- Costs of animal care

  - -- Nonprofit biomedical research organizations reported expenditures of approximately $2.2 billion for biomedical research in FY '78. Approximately $800 million of this amount was for research projects involving the use of some laboratory animals, of which $571 million was furnished by grants and contracts from NIH.

  - -- In spite of the increase in biomedical research funds, recovery of animal care costs has not kept pace with actual costs. User fees, including per diem costs, vary widely and do not appear to have achieved the level of cost accounting that is necessary to ensure an equitable distribution of costs on a direct-charge basis.

Implementation

- Completed in March, 1980, the information from this survey has been incorporated in the DRR research planning process. The results have formed the major basis for proposing a greatly expanded program to assist nonprofit biomedical research organizations in meeting their needs for modern animal facilities. Estimated to require funding at a level of $30 million per year beginning in FY '83, the program includes construction of new facilities on a 2:1 (Federal to local) basis. The survey results have also influenced current program priorities, including increased emphasis for research involving laboratory animal disease problems, continued support of diagnostic laboratory activities, and decreased emphasis for maintaining special colonies of research animals. Within funds available to the program, an expanded program of training, including increased research opportunities for specialists in the field of laboratory animal medicine will also be supported.

Reference

National Survey of Laboratory Animal Facilities and Resources, FY 1978, Committee on Laboratory Animal Resources and Facilities, Institute of Laboratory Animal Resources, National Academy of Sciences, 1980, EDC.

16

NATIONAL LIBRARY OF MEDICINE

Dr. Martin M. Cummings, Director

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Proposed Budget

		Dollars in Thousands FY 81	FY 82	FY 83
NLM 77-2a	Regional Medical Library Program: Data Gathering	--	--	--
NLM 77-2b	Evaluation of the Regional Medical Library Program	--	--	--
NLM 78-3	Evaluation of the Information Transfer Project	--	--	--
NLM 79-302	Analysis of Requests for Interlibrary Loans for Serials	(--)	(5)	(--)
NLM 79-303	Characteristics of AVLINE Use	--	70	70
NLM 80-401	Evaluation of Medical Library Resource Project Grant Program	(8)	--	--
NLM 80-402	Consultant Review of Lister Hill Center Programs	(10)	(10)	(10)
NLM 80-403	Consultant Review of MEDLARS III	(25)	(25)	(25)
NLM 80-404	Medical Library Assistance Act Program Performance (Several Evaluations)	(8)	(NYD)	(NYD)
NLM 80-405	National Medical Audiovisual Center Internal Program Evaluation	(20)	(20)	--
NLM 80-406	Computer Performance Measurement	(50)	(50)	--
NLM 81-401	Feedback Survey of NMAC's Film Videocassette Loan Program Clients	(5)	(5)	--

(cont.)

Proposed Budget (continued)		Dollars in Thousands FY 81	FY 82	FY 83
NLM 82-301	Online Services User Study	--	50	--
NLM 83-302	Evaluation of NLM's Services in the Behavioral Sciences	--	75	75
NLM 82-401	Analysis of Use of NLM Cataloging Data	--	(10)	--
	Total FY 82 Set-Aside Request		$195	

Notes:

( ) Non Set-Aside Funds
NYD Not Yet Determined

Policy Overview

The major mission of the National Library of Medicine is to assist in satisfying the information needs of health care practitioners, biomedical researchers, and educators. Within this mission NLM has identified four objectives: the expansion and improvement of library and information services at NLM and throughout the Nation; the improvement of information transfer for research, education, and health care; the creation of a center of excellence for research and development in biomedical communications in the new Lister Hill Center building; and the improvement of information transfer for the protection of health.

NLM has been heavily involved in evaluation activities of an evaluative nature for many years, and draws on the results of evaluation for planning and management decision-making. The scope of these activities runs the gamut from the overall policy development and program evaluation undertaken by the Board of Regents to detailed project evaluations.

The NLM Board of Regents meets three times a year to review and evaluate ongoing programs, advise the Secretary, DHHS, on major policy questions, and review NLM grant applications. The Board is informed of evaluation activities by NLM staff. The Board's subcommittees provide intensive review and advice for NLM programs. Several other advisory groups provide review and evaluation of NLM programs, including the Biomedical Library Review Committee (for NLM's Extramural Programs) and the Toxicology Information Program Committee of the National Academy of Sciences. It is anticipated that the newly established Board of Scientific Counselors will provide scientific guidance and evaluation for NLM's research and development programs. NLM's users provide continuous feedback on the quality and timeliness of the services they receive.

Internal NLM management focuses on improving program performance through continuous evaluation activities. NLM's senior staff meets daily to assess programs and resolve difficulties. Weekly staff meetings focus on critical issues for NLM management including evaluation of NLM programs. Each program produces monthly reports which contain quantitative and qualitative performance data that are carefully reviewed by the senior staff. The NLM Contract Review Group meets regularly to evaluate proposed contract actions within the framework of program plans and performance. The Director holds quarterly program performance briefings with formal presentations by each Associate Director which provide him with additional information upon which to evaluate each program. The issues identified in these activities provide input for a continuously updated compilation of NLM issues and policies which has become a major planning and evaluation tool.

Individual program managers have initiated many evaluation projects. These have been conducted either in-house or by contract, with both NLM and set-aside funding. All of NLM's division level components have been directly or indirectly involved in evaluative activities. The Office of the Director provides program direction and administrative support for the evaluation program as well as conducting evaluations itself.

The Associate Director for Planning in the Office of the Director is the focal point for the coordination and administration of the evaluation program. This office determines priorities for evaluation planning and suggests appropriate studies to NLM components. Within this framework, each program component makes proposals for the use of available program evaluation resources; those proposed projects which will provide the greatest benefit as determined by the Office of the Director receive highest priority in the the evaluation plan. The recently established planning process for NLM includes an audit/evaluation step for all major milestones in each project.

The progress of evaluation projects will be carefully tracked by the Office of the Associate Director for Planning, OD, NLM. Each evaluation report will be reviewed as completed to ascertain how the findings meet information needs and how it may be utilized with the appropriate NLM staff and other users.

NLM Program Performance Evaluations

NLM has previously completed a number of program performance evaluations and plans several more for the near future. They are described below. These performance evaluations have included the definition of program objectives and performance indicators and have provided evidence of the extent to which these programs are operated as planned. For many of NLM's programs, the production of program performance summaries to present these past evaluations in a concise manner is all that is needed. Often these studies have been planned and performed in a context other than program evaluation and thus have not been included in a request for approval as part of an NLM Evaluation Plan. However, we believe that these studies fulfill Departmental requirements and at the same time provide valuable information for NLM management.

FY 1982 Evaluation Plans

a. Office of the Director

The NLM Office of the Director plans several studies for FY 1982 which will evaluate selected aspects of NLM library services.

The first study (NLM 82-301) will examine the characteristics of NLM's online user community. Information is needed about who the users of NLM online services are, what the purposes of their searches are (i.e., developing research protocols, specific patient care questions, etc.), and how much online search experience the users being studied have. More details on this study will be forthcoming in Part II of the NLM Evaluation Plan.

The second study (NLM 82-302) will evaluate whether the bibliographic services and other programs of the Library meet the current needs of medical behavioral science, including anthropology, human psychology, sociology, and demography. The adequacy of the Library's scope and coverage in these subjects was last reviewed in 1967 by a special Task Force of the National Research Council. In the years since 1967, the amount of research and publication in medical behavior science has been increasing rapidly.

Furthermore, the scientific content and the methodological emphasis of these fields has changed substantially.

The evaluation will include the following areas of inquiry:

- Study of on-line users of MEDLARS in the behavioral sciences (probably as part of a broader study of on-line users described below).
- Study of reading room users.
- Study of MEDLINE coverage in behavioral sciences, including comparison of recovery of criterion bibliographic data using MESH/MEDLINE and alternative search techniques and/or data bases (e.g., Psychological Abstracts, Sociological Abstracts, Social Science Citation Index, etc.).
- Study of MEDLINE searches in the behavioral sciences, including the development of strategies and measurement techniques for assessing on-line search performance (where conventional measures of recall and precision may not be appropriate).
- Comparative studies of indexing languages, assessing efficiency and completeness.

b. Regional Medical Library Program

The Regional Medical Library (RML) program is a national network of 11 regional libraries, more than 100 resource libraries, and approximately 3,000 basic units (e.g., hospital libraries) coordinated by the National Library of Medicine. The network provides access to information in support of health services delivery, education, and research. Supported by 10 contracts (NLM functions as the 11th RML), network libraries share their resources through document delivery, bibliographic access to journal and monograph information, and cooperative acquisitions and cataloging. Regional libraries also promote network participation through consultation, training, workshops, and continuing education programs. Serious consideration is being given to reducing the number of RMLs and further encouraging self-sufficiency in order to make the network more cost-effective.

In light of these considerations, a comprehensive program performance evaluation of the Regional Medical Library Program is underway (NLM 77-2b). The study is evaluating the performance of the libraries participating in the network for the provision of services to the health professional community to determine if services are being carried out in the most efficient and cost-effective manner. It will also provide information and delineate alternatives so that the NLM can determine what changes in programs, policies, and regional configuration should be considered to improve that performance in the future, given budgetary and operating constraints within the NLM and participating institutions, and technological and networking advances in the field of information dissemination.

c. Lister Hill National Center for Biomedical Communications

The Lister Hill National Center for Biomedical Communications performs research and development to create new, or modify existing, biomedical communication systems and networks. These systems and networks are designed to improve the dissemination and utilization of information for the benefit of health services delivery, health education, and biomedical research. Emphasis at the Center is on experimental programs rather than on operating proved systems. With the facilities provided in the new building, the Center is carrying out more research and development with its own staff and laboratories, although collaboration with the outside biomedical science and technology communities will continue.

On October 10-12, 1979, the Lister Hill National Center for Biomedical Communications underwent a second annual review of its research and development programs by a group of scientific evaluators (NLM 80-402). The four programs reviewed were the Knowledge-Base Program, Integrated Library System, Videodisc Mass Digital Storage, and Electronic Document Storage and Retrieval. The reviewers found the research programs to be both significant and appropriate and made specific suggestions concerning program emphasis and direction.

On April 30 - May 1, 1981, the newly formed NLM Board of Scientific Counselors will meet for the first time to provide policy guidance and external peer review to the scientific research programs of the Lister Hill Center. The programs to be reviewed include:

- Document Storage, Retrieval, and Distribution
- Videoprocessing Laboratory
- Integrated Library System
- Digital Videodisc
- Distributed Information Delivery
- Advanced Terminal System
- Knowledge Base Program

The results of this meeting will be incorporated into the ongoing program performance evaluation of the Lister Hill Center.

An ongoing project of the LHNCBC (NLM 78-3) is the testing and evaluation of a prototype information transfer system (Knowledge Base) for practitioners. The evaluation is concerned with the effectiveness and efficiency of the processes for generating, validating, and updating the information bank contents, as well as with the retrievability of the information. It will also examine the usefulness of the information bank derivative products as information sources for medical decision-making and medical education, among other possible applications. This will provide one basis for determining how the information transfer needs of the biomedical community can best be served by R&D programs of the LHNCBC. Final results of the evaluation will be available by the end of 1981.

A program performance summary for the Center was submitted to the Office of Program Planning and Evaluation, NIH, in February 1981, for transmittal to the Office of the Secretary.

d. Library Operations

Library Operations, the largest of NLM's components, selects, acquires, catalogues, indexes, provides access to, and disseminates the material in NLM's collections of medical books, journals, documents, etc. Library Operations comprises four operating divisions - Bibliographic Services, History of Medicine, Reference Services, and Technical Services as well as Medical Subject Headings (MeSH) Section.

MEDLARS III, currently under development, is a comprehensive automation program which will serve the Library's operational and service requirements for the 1980s. The new system is intended to improve, extend, and integrate internal operations (such as technical processing of books and journals) as well as external network responsibilities. In this regard, MEDLARS III will provide new capabilities to help the Nation's health science libraries create bibliographic records, retrieve bibliographic and text information, have access to national holdings and location information, and order documents on interlibrary loan. Design and implementation of MEDLARS III will be a major NLM effort for the next three to four years.

MEDLARS III planning will provide an opportunity to examine basic issues and challenges facing library and information systems and to address the policy decisions facing NLM with regard to its role in emerging national networks. This activity will provide NLM Library Operations with a significant evaluation of program performance as the development of the new system requires extensive analysis of current operations and a delineation of alternatives for the future. The MEDLARS III development team is analyzing functions to be automated by breaking down the tasks into even smaller and more comprehensible subtasks. This analysis and documentation is providing valuable insights into the nature of Library Operations activities. The development of MEDLARS III is being carefully reviewed by staff, the Board of Regents, and constituent groups such as the Association of Academic Health Sciences Library Directors, the Medical Library Association, hospital librarians, networking experts, etc. (NLM 80-403). These reviews will lead to further refinement of the plans for MEDLARS III development.

A current problem requiring evaluation is cataloging. NLM acquires more materials than it is able to catalog fully. To make intelligent decisions about which items should get full treatment and which can be given limited cataloging, NLM must know which categories of its cataloging records are most heavily used by other biomedical libraries. To make the best use of scarce resources, NLM should provide full cataloging for categories of material also acquired by many other biomedical libraries and use limited cataloging to announce the availablility of less commonly held items in the NLM collection. To gain information on the use of NLM cataloging by Resource libraries, an evaluation of recent cataloging records from a representative group of Resource libraries is needed (NLM 82-401). The analysis should include statistics on the number of items cataloged by subject, language, and age and indicate whether NLM cataloging was available at the time the items were cataloged or subsequently.

e. Medical Library Assistance Act

NLM has six grant programs authorized by the Medical Library Assistance Act (MLAA) of 1965. They are:

- Training Grants
- Research Grants
- Resource Project Grants
- Resource Improvement Grants
- Publication Grants
- Special Scientific Project Grants

NLM is evaluating its Training Grant program in health sciences and computer technology which has been in existence since 1972. A program performance summary will be available in September 1981.

The Research Grant program was evaluated by an ad hoc group of consultants chaired by Dr. John F. Sherman in 1977. The task force concluded that more qualified investigators are needed in biomedical communications and that there is a need for increased research in the utilization of computers in medicine. As a result, NLM has initiated New Investigator Awards, Research Career Development Awards, and research project grants in these areas. Performance data for these grants will be collected and analyzed by FY 1984.

NLM 80-401 is looking at the impact of Medical Library Resource Project Grants in the health science library community. From 1971 to 1978 approximately $14.5 million dollars have been expended in almost 900 awards to health science libraries for the purpose of improving information service activities. The evaluation is determining program impact, identifying areas of program modification, if needed, and recommending future activity in terms of present needs. Results will assure continued development of health information services and systems in the most efficient and effective manner possible. This study is being performed by NLM Extramural Programs staff.

The Publications Grants and Special Scientific Projects were reviewed by NLM staff in 1974-1976; program performance evaluations of these grants are planned for FY 1982-1984. Resource Improvement Grants were evaluated by NLM staff in 1974-1976. A program performance summary will be prepared for both kinds of Resource Grants by September 1981.

f. National Medical Audiovisual Center

The National Medical Audiovisual Center (NMAC) is the component of the National Library of Medicine with primary responsibility for planning and administering a national program to improve the quality and use of audiovisual learning materials in health professional education and practice.

In March 1980, NMAC moved from Atlanta to the new Lister Hill Center building in Bethesda. The major programs of NMAC--Educational Materials Development, Media Utilization, Training and Consultation, and Educational Research and Evaluation--are either completely operational or expected to be so in FY 1981. The physical integration of NMAC facilities, programs, and expertise with those already existing at NLM created a number of new opportunities for improving and increasing services to NLM constituents.

Evaluations of two activities of the National Medical Audiovisual Center have been conducted. Analysis of the performance of NMAC's media distribution program has included two surveys of NMAC film loan and videotape users (NLM 77-3 and NLM 73-2) and an in-house analysis of the shareability of audiovisual resources. NMAC's training program in the use of instructional technology for health professional education has also been evaluated (NLM 78-4).

In the years that NMAC has provided 16mm. films and videocassettes on loan to health professions educators, relatively little has been known concerning the ways in which materials were used, user satisfaction with the service itself, or their satisfaction with the quality and content of the materials received. To obtain such "feedback," a relatively modest in-house survey will be conducted among a sample of loan program clients during an 18-month period that extends into FY 82 (NLM 81-401).

NLM 79-303, Study of the Selection and Acquisition Process of Audiovisuals by the Health Education Community, is a deferred project that will be undertaken in FY 1982. This study will look at what reference tools, including AVLINE (NLM's online audiovisuals data base) are used in the selection and acquisition of audiovisuals and how this process might be improved.

In FY 1982 NMAC will develop the methodology and collect internal and externally available data and other evidence to describe and evaluate its program performance (NLM 80-405). Criteria and evidence which will provide performance measures beyond standard indicators used for management and individual in-depth analyses of areas without identifiable measures are planned. The results of previous program evaluations and analyses will also be included. A program performance summary will be prepared by December 1982.

g. Specialized Information Services

Specialized Information Services' major responsibility is the operation of the Toxicology Information Program (TIP). The objectives of this program are (1) to create computer-based toxicology data bases from the scientific literature and from the files of collaborating industrial, academic, and governmental organizations and (2) to establish and operate toxicology information services for the scientific community.

The National Academy of Sciences, National Research Council, has provided evaluation and advisory services to the Toxicology Information Program (TIP) through its Toxicology Information Program Committee (TIPCOM) since 1969. TIPCOM evaluates the performance of the TIP in providing information services and recommends improvements in program performance. A program performance summary was submitted to the Office of Program Planning and Evaluation, NIH, for transmission to DHHS in February 1981.

In FY 1982, the Division of Specialized Information Services proposes to evaluate certain SIS projects by means of a contract with an appropriate organization which would represent a cross-section of the biomedical community (NLM 82-402). The first project to be evaluated by this mechanism would be the Toxicology Data Bank (TDB). Specifically, a one-year contract is proposed which would require at least three scientific analyses (evaluations), culminating in reports. These might deal with the following issues: (1) user assessment of the TDB; (2) use of the TDB as an information resource for chemical hazards in the laboratory; and (3) use of the primary literature or criteria documents as a source of data for the TDB.

h. Office of Computer and Communications Systems

The Office of Computer and Communications Systems (OCCS) provides data processing and data communications support for all elements of the Library. It has a critical supporting role for Library Operations as well as Specialized Information Services. Systems analysis and programing support are provided by computer analyst/programers who work closely with subject area specialists to determine their data processing requirements and to convert these requirements into new or improved data processing capabilities.

The performance and limitations of NLM's computer system was the subject of several studies and the assignment of a consultant under the Intergovernmental Personnel Act at NLM (NLM 80-406). The consultant developed an ongoing data collection and reporting system which will provide NLM management the necessary information to analyze the performance of the computer system. Implementation of this system is under way and a program performance summary will be prepared by July 1981.

NATIONAL LIBRARY OF MEDICINE

Evaluation of the National Medical Audiovisual Center Media Distribution Program

Definition and Description of Program

In keeping with the National Medical Audiovisual Center (NMAC) mission to support and improve health professions education through the use of audiovisual and related technologies, NMAC has established a program of media materials distribution which, at the time of the subject study, held and loaned to eligible health professionals and organizations about 900 16-mm film titles. In all, about 18,000 film prints were used to service about 40,000 loan requests per year. In addition, the program loaned about 250 titles as 3/4 inch videocassettes, servicing about 3,000 requests per year. The program also offers for sale (through the National Audiovisual Center, General Services Administration) a variety of instructional units, with NAC sales totaling about 3,000 units per year. The costs of operating the distribution program during the year of the subject study are estimated to be $430,000.

Evaluation Study

Design of Study

Of those requesting materials on loan, about 2,100 film borrowers and 450 videocassette borrowers were sampled and were sent survey questionnaires. From those securing materials through NAC, a sample of about 430 was chosen. The returned and usable questionnaires represented 56 percent of the film sample, 36 percent of the videocassette sample, and 29 percent of the NAC sales sample.

Results of Data Analyses

The main users of the film loan program were from nursing (37 percent of the users), allied health/"other" medical professionals (31 percent), nonmedical faculty (12 percent), while physicians and dentists accounted for 7 percent; the users' institutions were "other" (26 percent), hospitals (22 percent), nursing schools (19 percent), nonmedical colleges (15 percent), allied health schools (11 percent), and medical or dental schools (5 percent). The dominant use of the films was for classroom or lecture support (73 percent), with all other uses accounting for a few percent each. The users rated the

NMAC service quite favorably (5.7 on a 7-point scale), almost as favorably as the "next most used" film service. Their ratings of the most recently borrowed film were highly favorable (e.g., content and production quality rated 5.7 and 5.3 on a 7-point scale, respectively.)

The videocassette borrowers appear to be a somewhat different group (e.g., 18 percent physicians, 7 percent dentists, 16 percent nurses, 34 percent allied health), and they come from a different mix of institutions (e.g., 8 percent from medical schools, 7 percent from dental schools, 8 percent from nursing schools, 13 percent from allied health, and 39 percent from hospitals). In almost half the cases, the cassettes were borrowed for classroom use and in 14 percent of the instances, self-study was the reported use. In rating features of the loan service, the cassette users were generally quite favorable (e.g., overall, they rated it at 5.5 on a 7-point scale); and in rating the most recently borrowed cassette, respondents were most impressed by "ease and convenience of use," rating this at 6.2. Quality and currency of content were rated at 5.3 and 5.2, respectively. Like the film borrowers, those borrowing cassettes tend to be regular users of the service, making multiple requests each year.

The sample of NAC material purchasers was somewhat smaller than the cassette borrowers sample (N=125 vs. 166), so these results must also be interpreted with caution. By institution type, the purchasers represented medical schools (18 percent), hospitals (17 percent), dental schools (about 2 percent), nursing (6 percent), allied health (10 percent), nonmedical colleges (10 percent), and "other" or combinations (37 percent). The disciplines of the main users of the purchased materials were allied health/other medical professionals (22 percent), physicians (21 percent), and librarians (16 percent). The materials were intended primarily for classroom-lecture support (43 percent), self study (27 percent), and discussion-seminar use (10 percent). As with the two other samples, the purchasers have quite favorable attitudes toward audiovisuals and they give favorable ratings to the NAC services (e.g., overall, 5.3 on a 7-point scale); they also assign high ratings to the materials purchased.

Recommendations

1. Consider how to enlarge the distribution program clientele.

2. Consider maintaining a master list of NMAC catalog recipients and advise them of new editions, as issued.

3. Consider expanding the use of promotional flyers dealing with loan program materials-services.

4. Consider how dental professionals might be made a larger part of the program clientele.

5. Consider undertaking a formal needs assessment to identify varieties of materials which should be placed in distribution.

6. In new acquisitions, emphasize demonstrations and other distinctly visual presentations; deemphasize straight lectures.

7. Consider how to capitalize on the advantages of new audiovisual technologies such as cassettes and videodiscs.

Implementation

The first three recommendations of the study relate to issues of promotion and publicity. The following actions have been taken:

- (January 1981) Addition to Materials Utilization Branch staff of person responsible for developing, managing, and/or coordinating all promotional activities relating to distribution services.
- (January 1981) Development of FACTSHEET on new Videocassette Interlibrary Loan Service.
- (May 1981) Preparation of "List of Videocassettes available from NMAC."
- (July 1981) Publication of new edition of the National Medical Audiovisual Center Catalog: Films for the Health Sciences (available from GPO: $7.00).
- (July 1981) Design and printing of brochure and order form for the new catalog.
- (July 1981) Final circularization of old NMAC mailing list on soon-to-be obsolete equipment. Transfer of updated mailing list to, and continued expansion through, new online NMAC file and existing NLM file.
- (Ongoing) Publication of articles, news releases relating to services: presentations at national meetings, etc.

The fourth and fifth recommendations relate to NMAC users. The Materials Utilization Branch, in collaboration with the Educational Research and Evaluation Branch, has proposed two studies that will attempt to undertake a formal needs assessment and the use by health professionals of audiovisual materials (proposals attached). The addition of health professionals in dentistry and medicine (in addition to a nursing professional already on the staff) to the NMAC staff will assist in this needs assessment. The current development and/or use of internal online management files to track all loan data will allow us to provide statistical analysis of collection use, user profiles, etc., on an ongoing basis. In the past, all data collected resided in manual files, making manipulations of data impractical.

- (July 1981) 18-month survey (via OMB-cleared survey form) of 16-mm and videocassette loans to assess effectiveness of titles in loan programs.

The sixth recommendation relates to acquisitions. The procedure for adding new titles to the collection has changed. All new additions require a favorable AVLINE review before they can be made available. Since straight lecture-type audiovisuals are not reviewed, they would not be acquired for distribution. A detailed collection-building policy is being developed that will address procedural issues as well as the scope and currency of the collection.

The seventh recommendation relates to new technologies. A new distribution service for videocassettes was implemented in January 1981 for a 2-year experimental period. This service (now separate from the 16-mm film loan service, which is operated on contract in Atlanta) emphasizes a decentralized network approach to the sharing of audiovisuals, capitalizing on existing and well-established Regional Medical Library Network loan policies and procedures to the extent possible. Videodisc technology is being explored by NMAC as a potential mechanism for archival storage as well as distribution.

Effects of Programmatic Changes

NMAC's physical move from Atlanta to Bethesda in March 1980 disrupted ongoing distribution services for three months. The recovery period was slow because of extreme staff shortages. Most of the recommendations will be implemented during the summer of 1981; therefore, it is too early to determine the effect of any changes.

NATIONAL LIBRARY OF MEDICINE

Evaluation of the Public Health Service Communications Technology Satellite Program

Definition and Description of Program

From April 6, 1977, through June 27, 1979, the Lister Hill National Center for Biomedical Communications provided technical coordination and installation support for 20 experiments conducted by the Public Health Service, using the Communications Technology Satellite (CTS). CTS was capable of transmitting simultaneous, two-way color television programs between widely separated sites. Its high transmitting power and the use of a high frequency band (12-14 GHz) permitted the use of small, relatively inexpensive ground terminals, which have enabled various groups to engage in satellite-based video teleconferencing among ground stations located in Bethesda, Maryland; Bozeman, Montana; Denver, Colorado; Fairbanks, Alaska; Lexington, Kentucky; and Seattle, Washington. During its 818 days of operation the network logged 2082.7 broadcast hours. Over 16,000 people appeared before the cameras, logging a total of 46,372 participant hours. The approximate cost of this experiment to the Public Health Service was $6 million, shared between the National Library of Medicine and the Health Resources Administration.

Evaluation Study Performed

Design of Study

The Lister Hill Center contracted with the Metrek Division of the MITRE Corporation to conduct the system evaluation of these Public Health Service CTS applications. The sponsor and the user developed research objectives for each use of the satellite. MITRE's role as the system evaluator was to integrate the findings of these applications and to evaluate the results in terms of broader system-oriented objectives from which to base assessments of the future of satellite communications for disseminating biomedical information.

MITRE was asked to evaluate broadband satellite communication as a tool for supporting:

- The wide dissemination of health-related information

- Resource and curricular sharing among health education institutions
- Continuing education for health professionals
- Teleconferences in lieu of travel.

The Lister Hill Center conducted the technical evaluation. The satellite ground station, and studio-related parameters of the system's technical performance were measured during the biomedical applications. These were analyzed with respect to system performance objectives.

The objectives addressed included evaluation of:

- The channel quality throughout the Public Health Service CTS network in terms of the satellite-to-earth link performance and video and audio baseband signals.
- The availability and maintainability of the network.
- The capability of the network stations to operate in a wider geographic area or footprint than expected.
- The capability of the network to support dual video signal operation in one CTS channel.
- The capability of the network to support digital transmission over an audio channel simultaneously with video transmission over video channels.
- The extent to which the Bethesda station supported CTS users in conducting courses and teleconferences.

Results of Data Analyses

- For the first time, large numbers of people were exposed to communications satellite technology in biomedical applications.
- Satellite technology is highly reliable and is capable of

  --face-to-face interaction
  --graphic presentations and discussions
  --demonstrations of techniques
  --didactic lectures

- Geographic distances do not affect telecasts. This was reinforced by effective studio echo suppression and network management.
- Satellite communications provide opportunities for resource sharing between institutions.

- Satellite communications enable many students and professionals to interact with leading researchers and clinicians.
- Satellite-mediated instruction is as effective for learning as other modes, including in-person instruction.
- Two-way video is not needed for most didactic lectures. The extent of learning is not significantly different for two-way audio-video than for one-way audio-video with return audio. One-way video with two-way audio provides a satisfactory level of interaction.
- Two-way video is not needed except when the exchange of visual information is needed: medical procedure demonstrations, graphic material reviews, and complex problem solving.
- Commercial television production standards (e.g., sophisticated equipment and a large professional support staff) are not needed for effective teleconferences or teaching programs.
- Satellite video communications can be used effectively by teleconference and teaching participants with little specialized training.
- Commercial satellite-mediated video teaching and teleconference costs become very reasonable when distributed over large numbers of users, but the opportunity for interaction with presenters is inversely related to the number of participants.
- Based on designed levels of performance, the network demonstrated adequate link margins, and consequently high-quality reception of color video and audio signals, under both one-way and simultaneous two-way modes of operation.
- The link margins experienced were adequate to fully compensate for the adverse weather conditions encountered over the year for which detailed data were available.
- The specifications on important ground terminal elements such as the high power transmitter and low noise receiver could be relaxed with no perceptible degradation in performance. Substitutions could lower costs. Automated antenna tracking was convenient but not necessary.
- A satisfactory and cost-effective solution was found for the echo problem.
- The ground station equipment was highly reliable, although two items, the klystron and the phase-lock oscillator, needed more maintenance than expected.
- Malfunction of ground station or studio elements at non-Public Health Service sites, often due to incomplete checkout or inadequate calibration, caused the greatest loss of scheduled program time in 1978.

- Although the CTS's communication subsystem was well-suited for simultaneous interaction between two sites anywhere in North America, it was not designed to allow interaction with three sites. For example, site A in one footprint could not transmit both to site B in the same footprint and to site C in the other footprint covering another part of the country. This problem was solved by having C combine its own video signal with A's signal in a "split-screen" format, and retransmit the composite back to A and B. This allowed B to see both sides of conversations.

- Programs were successfully conducted involving Seattle, Bozeman, and Fairbanks in one footprint. This demonstrated that wider communication than had been expected was possible.

- It was found that, with some perceptible degradation, the high-powered band could be shared between two video signals. Several programs were successfully conducted using this feature, which was not originally designed into the system.

Recommendations Resulting From Study

The effectiveness and reliability of communications satellite technology have been demonstrated in a variety of biomedical applications and settings. What factors are likely to affect the future role of this technology in biomedical information transfer?

- The demand for medical information is growing. More course hours are needed for recertification, and the number of states and health specialties requiring continuing medical education is increasing.

- Satellite-mediated teaching and teleconferences have many competing alternatives.

- The most cost-effective use of satellites may require long-term capital investment for studio facilities and terrestrial communication links.

--Biomedical teaching and teleconferences via satellite require considerable intra- and interorganizational cooperation.

--Availability of fixed and mobile ground stations and terrestrial links will determine which cities, states, and regions participate in satellite-mediated biomedical communications.

Considering these factors, we have concluded that the mode will complement, but not replace, existing biomedical communication modes.

The following issues are recommended for further investigation:

- Comprehensive resource requirements for satellite applications, including costs such as coordination time, training for participants, and preparation of graphic materials.

- Resource requirements for satellite-mediated, compared to other teaching modes to aid health professionals and health educators as they consider continuing education alternatives.

- The use of communications satellites in administrative applications such as national and regional meetings for planning and budgeting for large health organizations.

Implementation

Two positive results have come from the CTS experiments. Certain users, such as the American Dietetic Association, have used their CTS experiences as the basis for the use of commercial satellites. Elsewhere in the Federal Government, the National Telecommunications and Information Administration is now in the third year of a program of grant support for further experiments, involving the Public Service Satellite Consortium and the use of commercial satellites.

Effects of Programmatic Changes

When planning for the CTS experiments began in 1975, NLM decided that the CTS was to be the Lister Hill Center's last satellite program. A subsequent decision eliminated the planned Poolesville remote antenna farm. Therefore, the recommendations of the evaluation have not affected NLM programs, but have contributed to and summarized this research effort.

NATIONAL LIBRARY OF MEDICINE

Evaluation of the National Medical Audiovisual Center

Definition and Description of Program

The National Medical Audiovisual Center (NMAC) conducts a national training program for health professionals through its Educational Consultation and Training Branch. Training activities emphasize the application of principles and concepts from instructional technology to the practice of health sciences education. The size of the training activity in support for staff salaries and training implementation is approximately $200,000.

Evaluation Study Performed

Study Design

The purpose of the study was to develop and field-test a set of procedures for NMAC use in evaluating its training program. The target audience was health professional teachers.

Specifically, the evaluation was to provide: (1) procedures and instruments for measuring the effectiveness of NMAC training activities in terms of health professional faculty performance; (2) procedures and instruments for assessing the attitudes and feelings of faculty with regard to training; (3) a procedure for obtaining feedback for the revision of training courses/materials and the reallocation of resources; and (4) a data collection system for the ultimate assessment of how NMAC training activities affect the delivery of health care services.

The evaluation study required the contractor to test procedures and instruments during two phases. The initial phase involved participant performance during and immediately after the training. The followup phase involved participant performance on the job. The contractor was required to validate procedures and instruments on a representative sampling of workshops.

Results of Data Analyses

The evaluation study resulted in procedures and instruments to collect the following types of information:

- Participant background information
- Feedback on training activities
- Feedback on skill objectives
- Content applications during workshops
- Content knowledge acquisition
- Workshop enhancement suggestions
- Workshop summary assessment
- Learner outcome achievement
- Program impact

Recommendations

The recommendations are reflected in the specific applications of procedures and instruments. These recommendations are too numerous to mention here. They can be found in one of the deliverables entitled "A Guide for Evaluating Learner-Oriented, Competency-Based Continuing Education Training Programs."

Organizational Response to Recommendations

The recommendations have been used as guidelines in the inhouse evaluation of the NMAC training program. The organizational response has been very supportive in pursuit of the goal of improving the NMAC training program through the systematic collection of feedback.

Implementation

Actual Changes Adopted

- More systematic collection of workshop feedback
- Integration of evaluation into the training feedback process
- Selection of more homogeneous groups for specific workshops
- Emphasis on followup of workshop participants
- Identification of the different decision-makers and the decisions they must make

Implementation Process

The implementation process consists of making the systematic collection of feedback an integral part of all program training efforts.

NATIONAL LIBRARY OF MEDICINE

Analysis of Interlibrary Loan Requests for Monographs

Definition and Description of Program

The National Library of Medicine (NLM) holds the world's largest specialized collection of biomedical literature. This material is available to other institutions on interlibrary loan (ILL) through the Regional Medical Library (RML) Network, a cooperative arrangement for the sharing of biomedical literature by medical libraries around the Nation. NLM, at the apex of the RML pyramid, serves as a backup to provide material not available regionally. In FY '80 the ILL program at NLM alone was budgeted at approximately $900,000. Although the major demand on NLM's loan services is for items from the journal literature, there is also a significant demand for monographs and congresses. In FY '80 the Library accepted approximately 30,700 requests for these types of material out of a total of 212,000. In support of NLM's document delivery program as well as of its broader mission to collect, organize, and disseminate the biomedical literature of the world, the Selection and Acquisitions Section in FY '80 administered a book budget of $302,000 to acquire an estimated 10,000 monograph titles. These are processed and cataloged in priority order based on NLM's assessment of the biomedical community's need for cataloging data and the anticipated demands on NLM's collection.

Evaluation Study Performed

Design of Study

Analysis of ILL Requests for Monographs was a small-scale study of interlibrary loan requests for monographs and proceedings of congresses approved for funding as part of the NLM FY '78 Evaluation Plan:

- To establish baseline data and a methodology for future evaluation studies in this area;
- To improve present program management through analysis of the characteristics of client institutions and their requests for document delivery measured against NLM's ability to satisfy such requests.

Because of its low budget (under $12,000) the study was designed to be accomplished through a combination of contract and inhouse work. The contractor drew a random sample of approximately 2,000 forms representing FY '78 interlibrary loan requests for monographs and proceedings of congresses. Both filled and unfilled requests were included in the sample. From each form data describing the requesting institution, requested material, and the disposition of the request were coded by the contractor and keyed to magnetic tape. NLM staff designed and mounted a special purpose study data base using INQUIRE software and produced tabulations and cross-tabulations to the contractor's specifications. By this stage the original contractor had gone out of business. To complete the remaining tasks--documentation of methodology, data analysis, and preparation of the final report--a personal services contract (under $3,000) was awarded to the individual who had been responsible for sample selection and data reduction. Her team manipulated the NLM-reduced tables, using anomaly detection as their principal strategy, and delivered both methodological and analytical reports.

Results of Data Analyses

The evaluation project provided the following:

- BKSTUDY, a special purpose data base using INQUIRE software and composed of 2,007 records coded from a random sample of FY '78 loan requests and proceedings of congresses.
- A description of the methodology used in sample selection and data reduction.
- A final report entitled Characteristics of the Interlibrary Loan Traffic in Monographic Materials at the National Library of Medicine.

The contractor successfully completed sample selection and data reduction, the major tasks in terms of labor and cost. This has recently been confirmed by a followup study undertaken inhouse to analyze NLM circulation data on monographs and congresses for the first six months of FY '81. These data, now collected in machine-readable form, closely parallel results of the earlier study. Thus the objective to establish baseline data for future comparison was met.

The final report was less satisfactory. Its analysis of the collected data makes assumptions and recommendations not warranted by those data. In addition, it contains a number of discrepancies and inaccuracies. As a result, the program office recommended that the report not be distributed in its present form.

Aside from the contractor effort, NLM staff undertook an independent analysis of data derived from the study. In general the findings confirmed predicted results as regards clientele and the characteristics and distribution of the material requested. NLM also performed an inhouse comparison of titles in BKSTUDY against the composition of CATLINE, NLM's data base of

material cataloged since 1965. The results showed a close correlation between the distribution of subject and publication language of items requested by libraries and of items cataloged by NLM.

Recommendations Resulting From Study

The program office recommended that

- The final report not be given wide distribution,
- Further inhouse analysis of BKSTUDY data be undertaken by concerned program areas,
- The Library investigate alternatives for handling requests for unowned congresses, monographs, etc.,
- Analysis of data for small scale studies of this type be done inhouse rather than on contract.

Response/Implementation

Annotated copies of the report and additional data tabulations, as requested, were made available to NLM staff involved in selection, acquisition, and cataloging of material, interlibrary loan, and Regional Medical Library Network program development.

According to the Chief of the Technical Services Division, the study confirmed data on the relative demand for various types of material particularly in regard to language, date of publication, and subject. It thereby contributed to the development of the limited cataloging program, which began in 1979, and the revised policy on cataloging priorities adopted in May 1981.

The RML Coordinator reports that data from the study demonstrating the relative self-sufficiency of the various regions contributed to a decision by the RML office to promote resource-sharing through technical services (e.g., the development of regional union lists, etc.)

To date no formal report has been submitted on inhouse analyses or use of study data; however, two followup projects are currently under way. One is an analysis of requests for monographs and congresses filled by NLM in FY '81, compared to the FY '78 data. It will be finished in September 1981. The second is an analysis of unfilled requests for monographs being undertaken in cooperation with the Selection and Acquisitions Section. It will be completed by October 1981. Appropriate data from both studies will be shared with the Regional Medical Libraries.

Recommendations on expanding NLM's role as a switching center to handle requests for titles which it cannot supply from its own collection and for developing a national locator service have been incorporated in the functional requirements for MEDLARS III. Implementation is still in the future.

NATIONAL LIBRARY OF MEDICINE

Evaluation of the Online Search Process

Definition and Description of Program

The online system of the National Library of Medicine is accessed by approximately 1,500 organizations in various health-related fields. Searches of NLM data bases are typically performed for the requestors or end users by search analysts. Organizations seeking to become members of the online network must send one employee for formal training in NLM-sponsored courses. Additional staff members may also be trained; however, about 50 percent of the analysts currently searching the system have received only informal on-the-job or in-service instructions. The purpose of this evaluation project was to assess the quality of searches being performed by both formally and informally trained analysts, to compare the efficiency and effectiveness of the two groups, and to correlate their performance with the specific type(s) of training received.

Evaluation Study Performed

Design of Study

An exploratory study to determine the relationship between the type of training that individual searchers of the National Library of Medicine (NLM) system receive and the searcher's style and performance was performed by Cuadra Associates and King Research. The study group included 191 searchers of the NLM system who were sampled according to three kinds of characteristics: (1) whether their training was formal or informal; (2) the type of organization in which they work; and (3) their search experience. Each searcher performed three of the 18 search problems used in the study that had been sampled from real search requests. Five hundred thirty-five usable searches were included in this study. The searchers reported also on the procedures used in conducting the searches. Recall and precision scores and time-related measures were used in the performance analysis. Special measurements of searching styles were developed for analysis of the online terminal printouts and implications for training, continuing education, and methodologies for ongoing self-evaluation by searchers were included in the report.

Results of Data Analyses

The conceptual framework for developing a measurement plan was based on a task analysis of the steps involved in the online search process. Searchers were evaluated not only on the quality of the searches they produced, but also on how well they performed certain tasks identified in this task analysis. An overall measurement plan was developed to outline in detail the performance measures used. This plan included:

- Primary Performance Measures

  --Quality: the standard methods of obtaining recall and precision ratios were used to measure overall effectiveness of study results;

  --Time: the amount of time taken in presearch planning, online searching, and postsearch evaluation was the principal measure of time and cost-effectiveness.

- Secondary Performance Measures

  --Procedures and Style: these two interrelated measures were developed to obtain some indication of whether a particular procedure identified in the task analysis was followed and, in selected cases, the ways in which particular items described in the task analysis were performed;

  --System-Use Proficiency: specific rating scales were developed to provide a measure of the efficiency with which the system capabilities and features are used and the types of errors that are made.

Searchers were evaluated both from the printouts of their online interaction and bibliography and from questionnaire responses.

Results of Data Analyses

- Performance Measures

  The performance measures of the online search process indicated that most searchers in the study population had mastered the basic techniques of using the NLM online system. The average scores across searches on the System-Use Efficiency rating scale were about 92 percent; the average scores on the System-Use Error rating scale were 97 percent. The average scores on the Dubious Practice scale were about 87 percent.

  Average recall scores of 23 percent and precision scores of 67 percent were reported. According to the contractor, these averages were not necessarily a conclusive measurement of searcher retrieval performance. Recall and precision scores may have been affected by the effects of mass (i.e., about 30 searchers per search) on the pool

of citations that was generated for inclusion in the "master bibliography" of each search against which recall and precision were measured. In addition, the reliability of the judgment of the panels of experts concerning a citation's relevance could possibly be challenged. The contractor recommended that further analyses of each effect be performed. The contractor did speculate on the possible "other" reasons for recall and precision scores, however.

- Effect of Search Request

  The primary independent variable that showed a consistent, significant effect on recall and precision scores in all the analyses of covariance was the search request itself. The search request did not, however, have a significant effect on search time.

- Effect of Training

  The type of training did not show any significant effect on either the time-related task variables or on the output variable, except in MEDLINE "hard" search precision scores. However, the contractor notes that these findings must look toward the definition of training used in this study before the conclusion can be drawn that training has no effect. The contractor hypothesizes that after a short period of time, perhaps as little as a few months, the major effects of training are modified by a number of factors such as motivation and other personal qualities.

- Effect of Experience

  Mixed results on the effect of experience on performance measurements were shown by the data. In the analysis of covariance, there were significant indications that experience, as measured by the average number of NLM searches, influences the amount of time it takes to conduct a search but does not influence search output. However, performance scores on the "Searcher Proficiency Index" indicated an effect on output of two measures of experience--length of time searching on NLM online systems and the average number of searches on NLM systems conducted per month.

- Effect of Organization Type

  In this study, organization type, e.g., research, patient care, etc., was identified as a source of variation in the amount of search time that was spent but not in the output measures. The output of the study searches did not appear to be influenced by the organizational setting of the requestor.

Recommendations Resulting From Study

The study was to obtain data pertaining to the online search process and the effect of training on searcher behavior, which could then be translated into

revised training and continuing education programs responsive to perceived user needs. The product received was an exploratory study of the online search process which includes: (1) observations on searcher behavior and effects of training and experience, (2) analysis of searcher performance using recall (the extent to which the search retrieved all of the relevant documents in the file) and precision (percent of relevant items in the search delivered to the requestor), (3) speculations on some of the study results, and (4) a discussion of possible implications of the major findings. The study, because of its exploratory nature, was not definitive and posed as many questions as it answered about the online search process and factors affecting it. However, until this study, little research had been performed on the search process itself, that is, on the qualities and characteristics of the intellectual activity involved in this highly individualized process. This lack of knowledge had made it difficult to design training programs that address the intellectual activity behind a search, which really produces a good search result, rather than the mechanics of the process itself. The findings and data recorded in this report represented a good first step in exploring this process and have provided a foundation or point of departure for further program evaluation.

Organization Response to Recommendations

In the final report, the contractor stated, "The translation of these study findings into actual program philosophies and components will entail additional work and study that are well beyond the scope of the present project..." However, the study did discuss the general implications of the findings on a training program. Many of the items discussed were already included in the NLM online training program. One not available at NLM was an ongoing self-evaluation system in which a number of searches would be included in a subset against which the searcher could evaluate his own retrieval. This could be done either in an online file or manually. Another area which NLM could emphasize is integration of the mechanics and the intellectual activity in conducting searches.

During the last year, the National Library of Medicine has begun a process of internal evaluation of the entire online training process. Education specialists on the staff of the Educational Training and Consultation Branch (ETCB) of NLM's National Medical Audiovisual Center are currently involved in an ongoing evaluation of the courses that make up the program. They will also evaluate the current computer-aided instruction programs available on the system and make recommendations toward improving the courses and, consequently, searcher performance. ETCB will work with the staff of the Training Program to implement changes based on these recommendations.

Implementation

Since the final report made no specific recommendations regarding online training or the search process, no implementation plan could be developed. NLM has begun an inhouse training program evaluation and will use information provided by the study, particularly in the task analysis, in this evaluation.

NATIONAL LIBRARY OF MEDICINE

Evaluation of Research Grant Program

Definition and Description of Program

The National Library of Medicine (NLM) and its component programs have been charged with an almost unique responsibility of national leadership for improvements in the delivery of health information services. The Medical Library Assistance Act of 1965 and its subsequent amendments authorize the National Library of Medicine to conduct a variety of extramural activities, one of which is a grant program "for purposes of carrying out projects of research, investigations, and demonstrations in the field of medical library science and related activities and for the development of new techniques, systems, and equipment, for processing, storing, retrieving, and distributing information pertaining to sciences related to health."

Evaluation Study Performed

Design of Study

In 1977 a Task Force on the Extramural Research Grant Program, chaired by Dr. John F. Sherman, was established to review research grants activity and the status of the field, and to make recommendations to the Director, NLM, and the NLM Board of Regents for any program modifications.

Results of Data Analyses

- NLM can take particular pride in the significant contributions which its intramural and extramural programs have made to improvements in biomedical communications.
- The projects supported by the Research Grant Program are of meritorious quality.
- Certain areas can be presently identified for research program emphasis because of a converging of programmatic need and research opportunity.
- Use of the merging technologies to improve biomedical communication will require long-range commitments to research and training.

- Although the broad scope of the Research Grant Program as mandated by the Medical Library Assistance Act and as described in the NIH Referral Guidelines is appropriate and desirable, uncertainty exists as to the nature of program goals and objectives.

Recommendations Resulting From Study

- Consideration should be given to the establishment of programs to provide research training for highly capable individuals dedicated to research in biomedical communications, and for attracting talented new researchers by providing appropriate interdisciplinary research environments and stable career paths.

- Major studies should be initiated in the area of new methods for representation of medical knowledge, frequently referred to as "computer-based medicine."

- NLM should obtain additional funding for the Research Grant Program to assure the desired advances in biomedical communications, and the long-term commitment stability needed for growth in this interdisciplinary field.

- The goals and objectives for the Research Grant Program should be reexamined and revised as soon as practicable and periodically thereafter, so as to provide definition of purpose for staff, potential applicants, and reviewers.

The NLM Board of Regents in May 1978 requested that the Extramural Programs staff develop specific plans to implement the recommendations.

Implementation

NLM initiated new programs to support career development for biomedical communications research (Research Career Development Awards and New Investigator Research Grants), and to support large scale studies in the field of Computers-in-Medicine (Program Project Grants). In FY 1979 NLM allocated over one million dollars to begin the new programs, and convened a special meeting of its Biomedical Library Review Committee to review applications. Funding was increased in FY '80 as a result of the Congress' designating $1.3 million for Computers-in-Medicine grant activities. The FY 1982-84 NLM Research Plan includes an additional $2.5 million for research grants. Referral Guidelines have been revised to reflect program changes.

Effects of Programmatic Changes

Fiscal Year 1979. Twenty-three Program Project applications were received and reviewed, of which six were eventually funded. Fourteen New Investigator proposals were reviewed and four subsequently funded. Six Research Career Development Award applications were reviewed and three were awarded. In all, thirteen awards were made for an amount of $1.5 million.

NATIONAL LIBRARY OF MEDICINE

Evaluation of Computer Performance and Capacity

Definition and Description of the Program

The computer operations activities of the NLM are critical to the provision of technical services, and in particular to the on-line information services to the health sciences community. Approximately 1,450 subscribers to NLM's on-line system, in the United States and in foreign countries, depend on this system for rapid access to bibliographic information in the health sciences. The large computer system that provides these services represents an investment of approximately $4 million. The computer, communications, and user services staff numbers approximately 60 full-time employees.

FEDSIM Study

Design of Study

In FY '76, the Federal Computer Performance Evaluation and Simulation Center (FEDSIM), under an interagency agreement with the NLM, evaluated the then-existing NLM computer performance management approach. The first objective was to determine the validity of data derived from the software performance measurement tools being used by the NLM. The second objective was to obtain baseline measurements of the existing operational system, upon which performance management decisions could proceed. The third objective was to develop an approach to computer performance management in the NLM, including organizational responsibilities and a multilevel performance reporting system, particularly reporting to senior management.

Extensive measurements were made using special equipment, documentation was analyzed, and many interviews were conducted in the data collection process.

Results of Data Analysis

The study verified that the existing performance measurement tools being used by the NLM were accurate, and that the basic data being collected were sufficient for performance analysis and reporting purposes. On the other hand, the study concluded that a new approach to performance management was needed if the performance of the computer resources was to be properly managed. Also, data relating to several technical parameters were analyzed to determine whether there were areas where performance could be improved.

Recommendations From the Study and Implementation

In addition to numerous findings regarding technical parameters and performance characteristics of the system, specific recommendations were made related to operating system alternatives and investigation of the possibility of optimizing application programs. These recommendations were addressed by the organization responsible for the computer operations, and changes were made that improved system performance.

As a key element in the new approach to NLM performance management, the study recommended establishment of a Computer Performance Management Administration (CPMA) to coordinate the overall measurement and management program. As an interim measure, a senior NLM staff member was assigned to perform this function part-time, to follow up on the FEDSIM study and determine the nature and extent of support required in this area. Subsequently, an expert was obtained, using the Intergovernmental Personnel Act mechanism, to further develop recommendations from this and the second study to be described.

The study also recommended that the NLM establish a multilevel reporting system, to be administered by the CPMA, and specific reports were identified. After the second study was completed, the aforementioned expert reviewed the studies and the NLM environment and recommended a set of management reports. These were approved in principle, and the computer operations organization was asked to determine the cost and effort of preparing them on a regular basis. This system was implemented in January 1981.

MITRE Study

Design of Study

In FY '79, a second evaluation, conducted by the MITRE Corporation under contract to the NLM, addressed the questions of computer capacity and capacity planning related primarily to NLM's on-line system. The first objective was to analyze the current system and its operation to obtain an up-to-date baseline description of the system and identify critical system parameters affecting capacity. The second objective was to review the state of the art in computer terminal workload simulation, and recommend a simulation mechanism to be used in testing the NLM system. The third objective was to assist NLM in designing the test plan and implementing the test. The fourth objective was to develop recommendations for an ongoing capacity test and planning system.

The study conducted in-depth reviews of previous studies, system documentation, and performance data, and included extensive interviews with technical and management staff of the NLM, to acquire initial data. Subsequently, a capacity test was conducted with MITRE assistance.

Results of Data Analysis

Critical system parameters were identified as part of an overall description of the system configuration and major elements. The study of available simulators revealed that there was no capability large enough to stress the NLM system. A live test developed jointly by NLM and MITRE was implemented over a two-day period.

Recommendations From the Study and Implementation

Several areas were recommended for further exploration by NLM staff regarding tuning of the system and/or obtaining additional software features. It was recommended that the simulator capability be pursued, particularly because there was an indication that NIH was interested in developing a simulator for its own purposes, sufficiently large to be of use to NLM.

From the capacity test results, it was concluded tht the computer system had sufficient inherent capacity to meet NLM internal and external user needs until the summer of 1981. This finding was important to NLM management because procurement of a new computer system was in process, and it was important to know whether the present system was adequate until a new system could be installed. Recommendations also addressed the management of capacity planning by the NLM. The results of this study and the FEDSIM study were used as a basis for refinement of NLM's overall performance measurement, management, and capacity planning system.

NLM Performance Management Information System

Design of Study

As a result of the evaluations described above, NLM designed and produced a computer workload and performance reporting and monitoring system for the National Library of Medicine's IBM computer and its on-line systems. This Performance Management Information System (PMIS) has now been implemented. The PMIS is intended to be of benefit to the levels of management concerned with the performance of NLM computing systems. This system was developed as an ongoing data collection and reporting system that provides top management with pertinent workload and performance information in the form of graphs, charts, and other statistical reports.

Results of Data Analysis

The PMIS was implemented in January 1981 in line with the recommendations of the previous studies for the types of data that would best characterize the workload and performance of the NLM system. Additional items were added to provide ways in which the raw data could be computed and presented in the form of sample charts and graphs. The majority of these charts and graphs have become a permanent part of the ongoing PMIS reporting system. These reports are being produced on a monthly basis and have been updated to include statistics to date. Special ad hoc reports may also be run upon

request to provide more specific information needed for management decisions and/or information. More specific information might include different time periods, specific file information, and information about different users or record types.

Recommendations From the Study and Implementation

The Performance Management Information System provides the information necessary for evaluation of NLM's ongoing data processing services. This system will be reviewed on a regular basis to assure that new evaluation requirements are processed effectively within the system.

Appendix

GUIDANCE FOR PREPARATION OF THE FY 1982 NIH EVALUATION PLAN

Program Evaluation Branch
Office of the Director, NIH

February 1981

GUIDANCE FOR THE PREPARATION OF THE

FY 1982 NIH EVALUATION PLAN

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GUIDANCE FOR THE PREPARATION OF THE FY 1982 NIH EVALUATION PLAN

INTRODUCTION

Planning for the FY 1982 Evaluation Program will follow the pattern of FY 1981. The plan can be expected to exhibit evaluation program activity development and should reflect somewhat increased emphasis on discussion of the utilization of evaluation results.

This year's NIH guidance calls for only minor revisions in forms and format. The two-part model is being retained, and it is expected that the review patterns established in FY 81 will also be repeated.

The NIH guidance is consistent with the details of the Department guidance in all essentials. The NIH guidance provides slightly different instructions for Tables and Forms. Please follow this NIH guide in preparing manuscripts. Models of Forms and Tables as they will be presented in the NIH plan will be found in the attachments.

Departmental Guidance

Departmental guidance for the preparation of FY 82 evaluation plans is attached. Following are salient points for consideration in the preparation of submissions for the NIH FY 82 evaluation plan:

- Evaluation plans--including strategy statements--should describe both evaluation projects to be funded from HHS program evaluation "set-aside" funds and evaluation projects funded from other sources; e.g., program funds, salaries and expenses, or research funds.

- Agency plans are to be submitted to ASH and ASPE on April 30 (Part I), and June 30 (Part II).

- The ASPE/ASH Part I review sessions with the NIH/BIDs will be held during May 1981; Part II reviews of specific project proposals will be held during July and August.

- Attachment I lists the now well-established criteria for eligibility for the use of "set-aside" funds.

The NIH Guidance departs from the Departmental guidelines with respect to the following details:

- The NIH budgetary listing of recently completed, ongoing and proposed projects differs from that described in Attachment I of the Departmental Guidance. The Program Evaluation Branch will prepare this Table from information submitted by the BIDs.

- The presentation order for projects in Part II of the NIH Evaluation Plan differs slightly from that given in the Department Guidance.

Organization of the Plan

The FY 82 NIH Evaluation Plan is to be developed in two parts; submission dates for Part II are staggered.

Part I - Includes a tentative budget, an overview of the BID's program evaluation strategy and activities, and brief descriptions of new projects proposed.

Submit to OD/PEB: April 15
(Departmental Due Date: April 30.)

Part II - Revised Part I, detailed Project Description and Justifications Forms, EDC description forms.

NIH OD Due Date(s): See Attachment II
(Departmental Due Date: June 30)

PREPARATION OF THE FY 82 EVALUATION PLAN

This section provides specific guidance for preparing individual Institute Evaluation Plans, which, together with the OD plan, will constitute the FY 82 NIH Evaluation Plan.

Outline for Institute Plan Submissions, Part I:

The following paragraphs outline suggested content and structure for BID Part I submissions:

Proposed Budget--Prepare a table to summarize current activities, expenditures, and plans for future funding of evaluation projects (both set-aside and institute-funded projects):

- List the titles of all projects for which FY 82 funds are requested.
- List also all ongoing projects whether or not additional funds are required in FY 82.
- Distinguish set-aside from other funds by enclosing amounts for non set-aside funding in parentheses. Footnote any interagency agreements or co-funding.
- Follow the format provided in Attachment III.
- This table should be placed immediately after the Table of Contents in the Part I submission (odd numbered page).

Policy Overview--Describe the Institute's program evaluation activities in the context of the BID's programmatic structure (e.g., the program structure listed in the FY 81 Evaluation Plan). Discuss the Institute's evaluation plans, activities and achievements in relation to this structure. Describe major evaluation projects underway or completed during the past two years, emphasizing the relationship of the evaluation to planning and program management. Indicate if part of the FY 82 evaluation effort is to involve implementation of previously approved but unfunded projects. Delineate questions and problems to be addressed in FY 82, and discuss implications of the proposed evaluations for the programs involved. Provide titles, paragraph length descriptions, and cost estimates for each new evaluation project proposed for FY 82.

Outline for Institute Plan Submissions, Part II:

The PART II submission containing detailed project descriptions should be presented in the following format:

Project Description and Justification Form--The NIH form is essentially the same as the FY 82 Department version. Attachment IV provides the format for the form to be used by the BIDs. The required information is

the same, including the question (Item #16) on paperwork burden. This form must be used to describe: (1) new projects being proposed in FY 82; (2) ongoing or new projects approved in prior years, but requesting additional funds (10% or $25k increase); (3) projects approved in FY 81, but deferred to FY 82 for implementation (to be revised as appropriate and indicated in item 16).

Ongoing and Recently Completed Projects--Ongoing and recently completed projects (December 1979 to present) should be described using the HHS Evaluation Documentation Center (EDC) Description sheet (Attachment V). Institute evaluation contacts must make sure that the EDC sheets on file in the Program Evaluation Branch, OD, are up to date and accurate. Complete instructions for filling out this form are found in the User's Guide to the HHS Evaluation Documentation Center, Summer 1980. This document is available from ASPE, NIH/BID evaluation officers, and the Guide to the NIH Evaluation Program, Section VI.C.

Presentation Order for Projects--The project descriptions should be presented in the following order:

(1) Projects that require use of the Project Description and Justification Form in chronological sequence;

(2) Projects that require use of the EDC Description Sheet in chronological sequence.

Chapter Assignments and Style Recommendations--Chapter assignments for the FY 82 NIH Evaluation Plan are unchanged from last year; they are as follows:

FY 82
NIH EVALUATION PLAN
Chapters

1. Introduction
2. Summary List of Evaluation Projects and Budget
3. OD
4. NCI
5. NHLBI
6. NEI
7. NIA
8. NIAID
9. NIADDKD
10. NICHD
11. NIDR
12. NIEHS
13. NIGMS
14. NINCDS
15. DRR
16. NLM

App. Guidance for the Preparation of the FY 1982 Evaluation Plan (Part I only)

The chapter number will be used as the first part in a two-part page number (e.g., 4.1, 4.2, etc.), for each Institute plan submission.

If possible, please use Letter Gothic Type.

Adherence to the following pagination and style recommendations will expedite preparation of the NIH Evaluation Plan and its subsequent printing. The first page of the Table of Contents, Budget Summary, Introduction, and, in Part II, each Project Description and Justification form, and the section composed of the EDC sheets, should all appear on the right side of bound volumes in which pages are printed on both sides. Therefore, these particular pages (right-side) should receive an odd page number and remaining pages (left-side) should receive an even page number. In addition, each Institute plan or chapter should have an unnumbered cover page. The format for the cover page is:

Chapter (number assigned to Institute)

1982 Evaluation Plan
(Institute name)

Part (I or II)

(name), Director

The page following the cover page should be used for a Chapter Table of Contents, numbered X.1 (where X = the assigned chapter number). Below is the suggested format:

(Institute Name) FY 82 Evaluation Plan

Table of Contents

Part I	Page No.
Institute Summary of Projects and Proposed Budget	X.3
FY 82 Evaluation Strategy Statement	X.5
Major Projects Underway or Recently Completed	X.X
New Projects Proposed	X.X

Part II	Page No.
Revised Part I	X.1
Ongoing Projects for which Additional Funds are Required and Approved Projects that have been Deferred to FY 82 for Implementation (Chron order)	X.3
New Project Proposals Mandated by Congress or the Secretary	X.5
Other New Project Proposals	X.7
Ongoing and Recently Completed Projects EDC Sheets	X.15

Note: For further explanation, see a copy of the FY 81 NIH Evaluation Plan, available in each BID Evaluation Office or from the Program Evaluation Branch, OD.

Institute Plan Submissions

Number of copies (Submit to PEB/OD)

Part I - 8 copies

Part II - 12 copies

For both Part I and Part II submissions, a sharp and clean "original" copy (suitable for photocopying and printing) should be sent to PEB/OD as soon as available following revision based on the Department review of the initial submissions.

For specific questions regarding the preparation of Institute plans, please contact the following staff members of the PEB/OD (Bldg. 1, Rm. 234, 496-4418):

Dr. Helen H. Gee--Guidance and Review Process, Part I submission

Gail Livings--Part II submission

Cindy Peters--Budgetary information

Sandy Cotter--Format and Style Recommendations

Attachment I

Eligibility Criteria for the Use of Set-Aside Funds

Types of evaluative activity eligible for the use of set-aside funds are:

1. Assessment of national health (research) programs: A range of approaches to program evaluation can be accommodated in this category--from determination of how the Institute program is affecting the "state-of-the-art" in a defined scientific subject area to comprehensive evaluation of the entire programmatic structure of an Institute. Assessments of program balance and program priorities are included in this category.

   "Program" evaluations are expected to provide information that will contribute to effective planning in terms of priority setting, resource allocation, etc. Distinguishing between "planning" and "evaluation" in proposal writing is often difficult, but a concerted attempt must be made to identify the evaluative component of the proposed effort and to estimate what portion of associated costs should be recovered from evaluation funds. An assessment of the "state-of-the-art," for example, meets the criteria of evaluation only if the assessment of a field of science is clearly and explicitly related to the program of activities supported by an Institute. In addition, the project should clearly show that it is part of an effort to evaluate program effects. Such evaluation generally involves a comparative or time series analysis using baseline data and data collected during subsequent intervals or at the conclusion of the program. Some of the topics that might be considered are: the relationship between the present portfolio of research activities and currently perceived research opportunities, the use of various support mechanisms, possibilities for the reallocation of funds, the redirection of policies that might affect advancement of the field, etc. Studies undertaken only to determine or demonstrate the need for new programs are not eligible for the use of set-aside funds. Basic research and health services research are not eligible for set-aside fund support.

2. Assessment of demonstration programs that have major implication for programs with national scope: Demonstration program evaluations may include assessment of effectiveness, costs, or public acceptance of demonstration activities. They may also involve comparisons between demonstrations that vary in their approaches to patient populations, etc. Evaluation of the performance of a single demonstration project is not eligible for set-aside funding but design of a method for evaluating demonstrations is.

3. Assessment of program or program management processes, techniques, or activities: Included are assessments of the efficiency, effectiveness, appropriateness, productivity, etc., of existing or alternative program support mechanisms (e.g., grants, contracts, centers, program projects, etc.). The development of techniques to be used by program staff to arrive at significant decisions concerning program direction or operation may also be the focus of a project.

4. Analysis or assessment of existing program policies to determine their impact on the activities of authorized programs: Included are studies of the effects on research production of alternative funding mechanisms; the effects on researchers, institutions, or on research support programs themselves of specific Federal policies; the effectiveness of review procedures; the impact on society of the development of particular technologies, etc.

   The assessment of prospective policies for the development of new programs is not considered eligible for evaluation set-aside funding.

5. Design and development of evaluation methods: The development and testing of new techniques or new approaches to evaluation are eligible, e.g., development of methods of analyzing scientific publications; development of methods for evaluating large, complex programs such as centers; development of techniques for assessing review procedures, etc. Assessment and analysis of program designs and activities devoted to securing more evaluable program designs are also eligible.

6. Design and development of information systems or data bases: This includes such projects as the development of a computer-based program information system aimed at expanding on data made available through the IMPAC system, or establishment of a data base that will permit tracking of program activity. The evaluative purpose of such information systems and data bases must be clearly explained. Such projects are eligible for the use of set-aside funds for two years only. The sponsoring unit is then expected to use operating funds to continue the activity.

7. Development of methods and procedures to be used for project review and monitoring (does not include support for on-site reviews or monitoring activities.)

8. Use of technical assistance to aid in the evaluation of eligible programs.

9. Short-term evaluation training of professional program evaluation staff.

10. Addition of evaluation questions to an ongoing general survey-limited to the managerial cost of the additional data collection and analysis of the evaluation information.

The following types of projects are not eligible for "set-aside" funding.

1. The evaluation of a single project (center, etc.).

2. The evaluation of an individual demonstration or experiment.

3. The continuing operation of management information or monitoring systems.

4. The continuing collection of baseline data.

Attachment II

Dates for Part II Evaluation Plan Submissions

Institute	Part II Plan Due Date (Draft)	Part II Final Revision Due
NCI	May 15	June 22
NHLBI	May 15	June 22
NEI	May 8	June 15
NIA	May 8	June 15
NIAID	May 15	June 22
NIAMDD	May 8	June 15
NICHD	May 15	June 22
NIDR	May 8	June 15
NIEHS	May 15	June 22
NIGMS	May 8	June 15
NINCDS	May 8	June 15
DRR	May 8	June 15
NLM	May 15	June 22

Attachment III

Institute Evaluation Plan Current Program and Proposed Budget
(Format Instructions)

Following is the format to be utilized by the Institutes for the Summary of Projects and Budget. If Institute funds are being used to support or co-fund projects, these amounts should be entered in parentheses and treated as a non-add item. Projects should be listed in chronological order.

- -

SAMPLE FORMAT

II. Office of the Director: Proposed Budget

	$ in Thousands FY 81	FY 82	FY 83
NIH 73-2 Evaluation of the Linkages Between Research Publications and NIH Funding	100	100	100
NIH 75-1 NAS Continuing Study of National Needs for Biomedical and Behavioral-Research Personnel	500	950	950
NIH 78-2 Identification and Characterization of Dissemination Pathways for Research Grants	60	150c	150c
NIH 78-5 Evaluation of the Impact of Clinical Trials on Medical Practice	75	--	-- (25)
NIH 79-301 Changing MD Participation in Research	125	75	--
Total FY 81 Set-Aside Fund Request		$1,275	

Notes

c - conditionally approved
( ) - non set-aside funds

- -

Attachment IV

NIH Evaluation Project Description and Justification Form (FY 82 Format)

1. Project Title: Title and a one-to-two-sentence description of the project.

2. NIH Evaluation Project Number: A unique number assigned by the Institute identifying the Institute, fiscal year of initiation, the source of funding, and the unique project number, e.g.,

   NHLBI 81-301 (will use evaluation set-aside funds)

   NHLBI 81-401 (will use Institute internal funds).

3. Agency Proposing: Agency and Unit (NIH-BID)

4. Cost and Funding Source: Indicate the appropriation to be used, e.g., set-aside funds or institute account. Also, indicate any DCRT (computer usage) charges separately. List as follows:

		DCRT
FY 81	$_____	
FY 82	$_____	
FY 83	$_____	
Future years	$_____	

   (BID funds in parentheses)

5. Program Evaluated: Name the program(s) being evaluated. Use the list of HHS program names which appears in the Summer 1980 edition of User's Guide to HHS Evaluation Documentation Center (see Attachment VI). Example: PHS-NIH-Biomedical Research - Intramural Research

6. Purpose: (a) Identify the type of evaluation study, e.g., program performance evaluation (evaluability assessment, short-term evaluation, full-scale evaluation), or other primary focus. (b) Outline the purpose of the proposed project. In particular, what policy questions will be answered, what hypotheses will be tested, and what findings are expected from the proposed study?

7. Related Work: Discuss related work completed, underway, or proposed which bears on the approach or expected impact of the project. Specifically indicate: (a) how the project will build on such work; and (b) how the project will provide additional information not now available to the Department. Show that no products already exist which could meet the objectives of the project by checking as appropriate, sources such as the Compendium of HEW Evaluation Studies, Summer 1980 Edition, the National Technical Information Service, other specialized information systems, and experts in other agencies.

8. Approach/Methodology: Describe the approach to be employed in the project. Include a discussion, whenever relevant, of the population to be examined; types of data to be examined or collected; data-gathering methods; analytic tools or techniques; and relationship of the study population to the total universe. Show that the approach proposed is likely to be adequate to support the expected results, and why it is selected over alternatives.

9. Primary Intended Users: Please state which one of the following descriptions best describes the primary intended users of the proposed study:

   (a) The evaluation is intended to meet the specific information needs of the HHS staff member requesting the study.

   or

   (b) The evaluation is intended to meet the information needs of the program managers and policy-makers responsible for the program being evaluated in order to improve the efficiency/effectiveness of that program.

   or

   (c) The evaluation is intended to meet information needs of a wider audience (e.g., Congress, OMB, State and local governments, the public) involved in debate on a specific policy issue. If (c), please specify the policy issue to be addressed and intended audience for the study.

   or

   (d) The evaluation is intended to meet some other information need. If (d), please specify the information need to be met.

10. Application and Utilization of Findings: Briefly describe the actions expected to be taken on the basis of the proposed evaluation study. Show that the intended uses of the study are important and significant enough to the Department to justify the project costs. Present plans for dissemination and utilization of the final product.

11. Date Project Description Prepared: Indicate if a revision of previous submission.

12. Execution: Indicate whether contract, grant, or in-house. Provide rationale for not doing project in-house if project is to be done under contract. Indicate the agency and Institute under which the project will be administered, start/end dates, phases, and end products.

13. Project Monitor/Contact: Name, office, address, and telephone number of the person responsible for developing work statement and for monitoring the project, if different.

14. Individual Requesting Project: Name person making initial request for project, or otherwise state origin of the project. State whether this project was mandated either by Congress or by the Secretary and cite the specific request.

15. Coordination: Identify the persons or groups in your Institute or in other agencies who have reviewed the project. Also outline any plans for project oversight. If the project was approved in FY 1981 but not initiated in FY 1981, so state.

16. Information Collection Burden: In order to facilitate preparation of the Department's "Information Collection Budget," indicate whether or not the project involves collection of identical data from 10 or more persons in fiscal years 1981, 1982, or 1983. If it does, please fill out the attached information collection budget supporting exhibit.

Attachment V

HHS Evaluation Documentation Center (EDC) Description Sheet
(FY 82 Format)

Project No.: (NIH Evaluation Project Number)

1. EDC ID No.: (Leave Blank)

2. Entry Dates: (Leave Blank) 3. Status: (Ongoing or Complete)

4. Project Title: (Short descriptive title of project – as approved)

5. Report Title: (Title(s) of final reports -- usually not yet determined for ongoing studies)

6. Agency Sponsor: (PHS-NIH-Institute Initials) 7. Start/End Dates: (Year and Month in the form 77-03, 80-01)

8. Performer: (Organization and address)

9. Agency Contact: (Name, NIH Building No., Room Number, Telephone No.)

10. Cost: (Cost by fiscal year(s) dollars in thousands in form FY 70-$45; FY 80-$30)

11. Fund Source: (Evaluation, S & E, etc.) 12. Mechanism: (In-house, Contract, etc.)

13. Project No.: (NIH Project No. - e.g. NCI 81-301) 14. Contract No.: (e.g. NO1-OD-6-2149)

15. NTIS No.: (NYD or EDC Only) 16. ERIC No. NA (Not Applicable)

17. Program(s) Evaluated: (According to the revised list of HHS program titles - see Attachment VI)

18. Evaluation Type: (Drawn from nine possible categories)

19. Descriptors: (Selected from a fixed thesaurus of possible key words)

20. Abstract: The abstract should describe the essential features of the study in 250 words or less. It should be oriented to the user who will be reading it to determine whether or not to look up the full report of the study. A good abstract will cover most of the following points:

- Why is the evaluation study being done? What purpose will it serve?
- What are the expected findings?
- What analytic techniques will it use?
- What types of data collection are involved?
- What is the target group or population involved?
- Any pertinent background information useful to a person who may not be an expert in the subject.
- Any special circumstances such as several agencies involved, a Congressionally mandated study, existence of related projects, etc.
- Method of study dissemination, e.g., journal publication, agency report, etc.
- Study results, conclusions, and recommendations (upon completion of study).

Attachment VI

Evaluation Program Index

Note: The following program index is taken from the User's Guide to the HHS Evaluation Documentation Center, Summer 1980.

National Institutes of Health

PHS-NIH-Biomedical Research (Entire Program Area)

PHS-NIH-Biomedical Research-Activity-Construction Grants

PHS-NIH-Biomedical Research-Activity-Disease Control

PHS-NIH-Biomedical Research-Activity-Intramural Research

PHS-NIH-Biomedical Research-Activity-Program Direction and Management

PHS-NIH-Biomedical Research-Activity-Research Grants and Contracts

PHS-NIH-Biomedical Research-Activity-Training (Entire Program Area)

PHS-NIH-Biomedical Research-Activity-Training-Fellowships

PHS-NIH-Biomedical Research-Activity-Training-Institutional Grants

PHS-NIH-Biomedical Research-Institute Specific-Aging

PHS-NIH-Biomedical Research-Institute Specific-Allergy and Infectious Disease

PHS-NIH-Biomedical Research-Institute Specific-Arthritis, Diabetes, Digestive and Kidney Diseases

PHS-NIH-Biomedical Research-Institute Specific-Cancer

PHS-NIH-Biomedical Research-Institute Specific-Child Health and Human Development

PHS-NIH-Biomedical Research-Institute Specific-Dental

PHS-NIH-Biomedical Research-Institute Specific-Environmental Health

PHS-NIH-Biomedical Research-Institute Specific-Eye

PHS-NIH-Biomedical Research-Institute Specific-General Medical Sciences

PHS-NIH-Biomedical Research-Institute Specific-Heart, Lung and Blood

PHS-NIH-Biomedical Research-Institute Specific-Neurological, Communicative Disorders and Stroke

PHS-NIH-Biomedical Research-Fogarty International Center

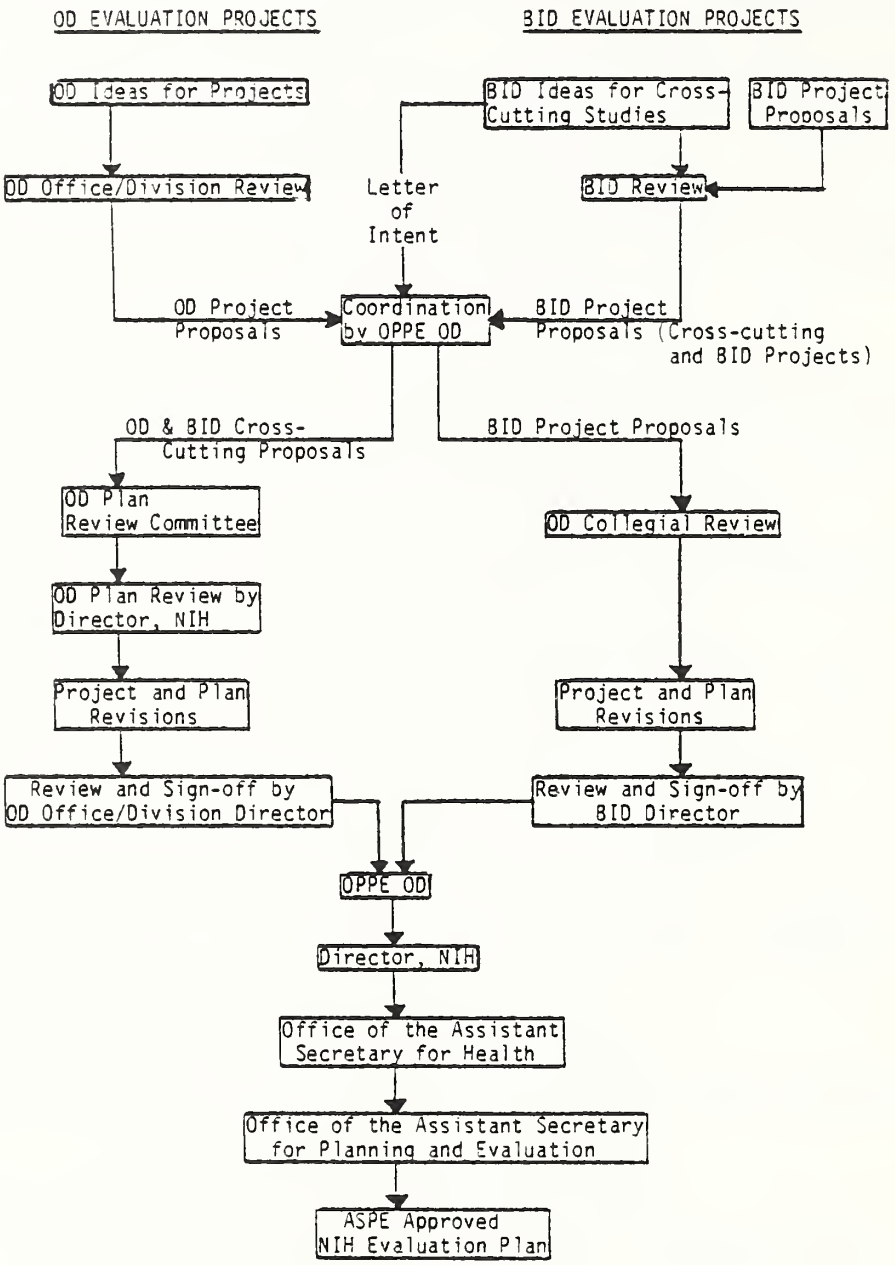
PHS-NIH-Biomedical Research-Library of Medicine

PHS-NIH-Biomedical Research-Office of the Director

PHS-NIH-Biomedical Research-Research Resources

Attachment VII

Concept Review of FY 82 NIH Evaluation Project Proposals


OD EVALUATION PROJECTS
BID EVALUATION PROJECTS
OD Ideas for Projects
BID Ideas for Cross-Cutting Studies
BID Project Proposals
OD Office/Division Review
Letter of Intent
BID Review
OD Project Proposals
Coordination by OPPE OD
BID Project Proposals (Cross-cutting and BID Projects)
OD & BID Cross-Cutting Proposals
BID Project Proposals
OD Plan Review Committee
OD Collegial Review
OD Plan Review by Director, NIH
Project and Plan Revisions
Project and Plan Revisions
Review and Sign-off by OD Office/Division Director
Review and Sign-off by BID Director
OPPE OD
Director, NIH
Office of the Assistant Secretary for Health
Office of the Assistant Secretary for Planning and Evaluation
ASPE Approved NIH Evaluation Plan

DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date 6 '81

From Deputy Assistant Secretary for Health Planning and Evaluation

Subject Departmental Guidance for FY 1982 Evaluation

To Agency and Staff Office Heads

This memorandum transmits the Departmental Guidance for FY 1982 Evaluation. As noted in the Attachment, Part II of the Guidance relating to evaluation policy will be issued by the incoming Administration. To assist the new Administration, we think it would be useful to convene a meeting in January of Agency and Staff Office Planning and Evaluation Officers to get your thoughts regarding the evaluation policy.

This opportunity for you to express your views will be in addition to that which you will have to comment on the draft of Part II of the Guidance.

You will be contacted next week for a mutually agreeable date for the January meeting.

Susanne A. Stoiber

Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

MEMORANDUM FOR: Assistant Secretaries
Heads of Principal Operating Components
Inspector General
Director, Office for Civil Rights

SUBJECT: FY 1982 Guidance for Evaluation Activities, Part I

This memorandum provides guidance for the planning and conduct of evaluation activities of the Department for FY 1982. Due to major changes in the Department's research planning process, a separate guidance on that subject will be issued early next year.

The Guidance for Evaluation will be issued in two parts for FY 1982. The attached Part I provides detailed instructions and a schedule for plan development and review for all evaluation activities. Part II, setting forth departmental evaluation policy, will be issued by the incoming Administration. Agencies will be asked to comment on the draft Part II Guidance prior to its issuance.

The Department has made much progress in the past year to help improve the performance of the Department's programs. Principal Operating Components have given high priority to program performance evaluations designed to clarify program objectives and to assess program performance in terms of those objectives.

In brief, the Part I Guidance sets forth the following:

- Heads of Principal Operating Components and the Director of the Office for Civil Rights are to now initiate planning for FY 1982 evaluation activities. Succinct POC/agency strategy statements are to be submitted to the Assistant Secretary for Planning and Evaluation by April 30, 1981, and will serve as the bases for discussion of evaluation priorities.

- By June 30, 1981, each Principal Operating Component and the Office for Civil Rights are to prepare draft evaluation plans and provide these to the Assistant Secretary for Planning and Evaluation for circulation to other POCs and appropriate OS staff offices.

- The Assistant Secretary for Planning and Evaluation will plan to complete review of all agency evaluation plans by September 30, 1981.

John L. Palmer

Attachment

FY 1982 GUIDANCE FOR EVALUATION ACTIVITIES

TABLE OF CONTENTS

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FY 1982 EVALUATION PLANNING PROCEDURES

A. Definition

Evaluation is the measurement of program performance (efficiency, effectiveness, responsiveness), the making of comparisons based on those measurements, and the use of the resulting information in policy-making and program management. Evaluations are intended, in particular, to assist program managers in decisions on program activities and objectives, including decisions on regulations, guidelines, and technical assistance, and to assist policy-makers in budget and legislative decisions.

B. Plan Content and Plan Review

The following types of projects are to be included in evaluation plans: evaluations of national programs or policies, evaluations of program management processes, and evaluations of pilot programs which have major implications for programs of national scope. (The following type projects are not considered program evaluation and should not be included in agency evaluation plans or reported as consultant services under General Administration Manual Chapter 8-15: evaluations of individual "R&D" experiments and demonstrations, evaluations of individual local projects, or research and development projects.)

Evaluation plans should include both evaluation projects to be funded from HHS program evaluation "set-aside" funds and evaluation projects funded from other sources: program funds, salaries and expenses, and research funds.1/

To allow for consistent reviews across agencies, evaluation plans are to be submitted in two stages:

1/ The term "set-aside" refers to programs whose authorizing legislation permits program funds to be used for evaluation of those programs. Criteria governing types of projects eligible for "set-aside" funding are presented in Appendix I.

1. Part I of the Plan (Evaluation Strategy Statement)

A brief overall discussion of the agency's FY 1982 evaluation strategy (10-15 pages). The strategy statement should be organized either by program or by Bureau or Division. The evaluation strategy should discuss:

--Major projects either underway or completed in the last two years;
--Evaluation objectives (which evaluation questions have priority in FY 1982, what are the primary intended uses of the resulting information);
--Paragraph-length descriptions of major studies to be undertaken in each program;
--Anticipated cost of each major project; and
--Anticipated total agency FY 82 evaluation spending.

DUE DATE: POCs, OCR, and ASPE are to prepare evaluation strategy statements (Part I of the plan) and submit six copies to ASPE by April 30, 1981.

Discussions among POCs, agencies, and ASPE concerning these evaluation strategy statements will be held during May 1981. Based on these discussions, the evaluation strategy statements are to be revised and resubmitted with Part II of the plan.

2. Part I and Part II of the Plan (Revised Strategy Statement and Project Descriptions)

The evaluation plan is to consist of the following: a revised Part I, reflecting the discussions among POCS, agencies and ASPE held in May; Part II, containing project descriptions; and Attachments to the plan.

Part II of the plan is to contain evaluation project descriptions, grouped in the following five sections:

(1) All new projects specifically mandated either by Congress or by the Secretary. (For each such study, cite the specific request in Item #14 of the Project Description.)

(2) All new evaluation projects.

(3) All continuation projects for which FY 1982 funds are required. (Continuation projects should be so identified in Item #4 of the Project Description.)

(4) Projects already approved as part of the FY 1981 plan but which are to be initiated in FY 1982. (Such projects should be so identified in Item #15 of the Project Description.)

The project description format is presented in Appendix II to the Guidance.

DUE DATE: Each Principal Operating Component, the Assistant Secretary for Planning and Evaluation, and the Director of the Office for Civil Rights will submit an evaluation plan (ten copies) to the Office of the Assistant Secretary for Planning and Evaluation by June 30, 1981.

During July and August 1981, ASPE will hold review meetings with POC and agency evaluation staffs to discuss agency plans. Upon the conclusion of the meetings, ASPE and POCs will transmit their formal review comments. As appropriate, ASPE will circulate agency plans to other POCs and offices for comment. Upon completion of the reviews, each POC should circulate information copies of the revised plan to all agencies within that POC, to other POCs, to the Office for Civil Rights, and to ASPE.

3. Attachments to the Plan: The following should be attached to the plan:

(1) Attachment I, listing all new and continuation evaluation projects:

—active in FY 81;
—proposed for funding in FY 82;
—proposed for funding in FY 83.

(2) Attachment II, listing evaluation dollar totals for FY 1981 and FY 1982.

Instructions on how to prepare each attachment are presented in Appendix II of this Guidance.

The Assistant Secretary for Planning and Evaluation will as appropriate, and in consultation with POC heads, establish necessary modifications in evaluation plan content.

C. Plan Amendments

As additional evaluation projects are developed during the fiscal year to meet program managers' or policy-makers' unanticipated information needs, POCs should submit project description and justification forms to the Assistant Secretary for Planning and Evaluation for review and approval.

D. Project Review

Agencies must have an internal review process to ensure that individual studies are well selected, well coordinated, and well designed. It is desirable that review occur at several stages of project development--project conceptualization, project description, and, for contracts, at the time of the RFP.

(A description of the project review process is not required in the evaluation plan, although ASPE may selectively request information on agency project review mechanisms.)

The project description and justification form presented in Appendix II provides a minimum basis for initiation of the project review process. All projects should be subjected to review by a small group or groups of highly qualified senior staff specifically charged with culling out projects which are not likely to result in useful information.

The review process should also safeguard against unconstructive duplication of projects, promote the integration of complementary projects, and ensure that:

- o projects further the agency's management and evaluation strategy;
- o the questions addressed in each study are answerable;
- o the methodologies are appropriate;
- o projects are adequately funded and will be adequately monitored;
- o the intended use is clearly and specifically identified;
- o the expected value of the study justifies its cost;
- o the choice of contracts versus in-house execution is appropriate.

APPENDIX I

EVALUATION PROJECTS ELIGIBLE FOR "SET-ASIDE" FUNDS

Questions frequently arise as to what criteria govern the types of evaluation projects eligible for evaluation "set-aside" funds. As noted in Section A, the term "set-aside" refers to programs whose authorizing legislation permits program funds (typically, up to 1% of program funds) to be used for evaluation of those programs.

In reviewing a project's eligibility for "set-aside" funding, the following criteria will be used:

Projects eligible for "set-aside" funds

1. Evaluation of HHS funded national programs.

2. Evaluation of demonstration programs which have major implications for design or redesign of national programs. (Evaluation of research and development "demonstrations" are generally not eligible for "set-aside" funding.)

3. Evaluation of program or program management processes, procedures, intervention techniques, or information systems, except those specific to a single local project.

4. Evaluation of existing policies to determine their impact upon programmatic activities or currently authorized programs. (The assessment of prospective policies, where no programs yet exist, is not eligible for "set-aside" funding.)

5. The design or development of general evaluation methodologies, as well as such methodology as may be developed for assessment of specific programs. Further, support for development of methodologies which may be implemented to assess individual projects is appropriate, and may include preparation of project evaluation manuals or handbooks for grantees. (However, the execution of these methodologies to evaluate individual local projects is not eligible for "set-aside" funding.)

6. The initial design and development of management information systems for programs of national scope. The use of evaluation funds to finance the design and development of such systems is limited to two years, starting from the design phase. After two years, agencies are expected to fund such systems from operating funds.

7. Initial development and pilot testing of instruments and procedures which, following development, will be used for on-site project review and monitoring. While such initial development and pilot testing is eligible for evaluation support, agencies are expected to fund ongoing monitoring systems from program funds.

8. Securing technical assistance to aid in or related to evaluation of eligible programs, excluding however, assistance to a single local project.

9. Short-term evaluation training of Federal employees whose professional concern is primarily evaluation of programs. (Evaluation training for state and local officials is not eligible for "set-aside" funding.)

10. The addition of evaluation questions to an on-going general purpose survey. However, the cost to be incurred by evaluation funds is limited to the marginal cost of adding the questions and analyzing the evaluation data. Proposed add-on projects will be reviewed according to the following criteria:

    (A) Evaluation is the primary purpose for the added questions, and that these questions would not be asked unless the evaluation were undertaken.

    (B) The information provided is essential to the evaluation of the program.

    (C) The desired information is not obtainable from other, more appropriate, sources.

    (D) The proposed add-on survey is methodologically sound with regard to the goals of specific evaluation projects.

    (E) The information to be gained from the study is "worth" the dollar expenditure involved.

Examples of projects not eligible for "set-aside" funds

As a general rule, the following types of projects are not eligible for "set-aside" funding:

1. The evaluation of individual local projects.

2. The evaluation of individual "R&D" experiments and demonstration projects.

3. The continuing operation of management information systems or ongoing monitoring systems. (As noted in #6 above, the use of evaluation funds to finance the design and development of management information systems is to be limited to a maximum of two years beyond the start of the design phase.)

4. The continuing collection of baseline data.

5. On-site review and monitoring of local projects. The development and pilot testing of instruments and procedures for on-site project review and monitoring is eligible for "set-aside" funding (as noted in #7 above) but the operation of ongoing monitoring systems is not.

APPENDIX II

EVALUATION PLAN CONTENT

All FY 1982 evaluation plans are required to contain specific attachments as stated in the Guidance. In addition, agencies are required to prepare project description and justification forms and include them in Part II of the evaluation plan, as discussed on page 2 of the Guidance. This appendix presents the required formats for the attachments and the project descriptions and justifications.

1. Project Description and Justification

The attached project description and justification form (pp. 11-14) is required for every evaluation project, whether in-house or contract, over $10,000. A set of these project description and justifications are to be included in Part II of the plan.

The project description and justification form covers not only the important elements of evaluation project planning, but also the information required by the current GAM Chapter 8-15 on consultant services policies and procedures.

Project descriptions and justifications should be as concise as possible (normally two or three pages). They should allow a professional who is not familiar with the subject to understand the rationale for a project and to make a judgment as to the probable usefulness and feasibility of the project.

In cases in which a particular item is not fully applicable, so state. For contingency projects not yet developed to the level of detail ultimately needed, indicate contingency nature and gaps.

The project description should be supplemented with additional information in cases in which this is warranted. In cases in which several projects are related, each project description should cross-reference the others.

The project description should be written in a style, format, and length (short) suitable for reproduction and dissemination.

No changes have been made in the FY 1982 Project Description format from the FY 1981 format. The required information is the same. The question (Item #16) on paperwork burden has been continued in order to obtain the information which will be needed to prepare the information collection budget requested by Executive Order 12174 on "Paperwork." Item 16 will be used to meet the OMB requests for project descriptions, creation of summary tables, and rationale for projects prepared.

2. Project List Format (Attachment I to Part II of the Plan)

Attachment I (p. 15) will present a capsule summary of evaluation projects either underway or planned in each agency. Among its many uses, the attachment will show which of the projects proposed for funding in FY 1981 have actually been awarded and are now underway.

The list of projects active in FY 1981 should include those projects either initiated, underway, or completed in FY 1981. The actual/estimated completion date (month/year) should be provided for all projects.

Only contracts over $10,000 should be presented as projects in Attachment I. Projects under $10,000, small purchase orders, computer support, inter-agency transfers, and personnel costs (S&E and consultants) should be indicated under "Other FY 81, 82, or 83 obligations." Contract modifications over $25,000 shall be treated by new projects and individually listed under "Projects Active in FY 81." The list of projects to be initiated in FY 1982 should be consistent with and include all project descriptions contained in the FY 1982 evaluation plan.

To make FY 82 and FY 83 estimates realistic, we have included a "slippage" line in Attachment I. Agencies are requested to deduct expected slippage from the dollar subtotal for all proposed projects. Slippage should also be taken into account when completing Attachment II.

The total spending entry for FY 81-83 must agree with the corresponding entries in Attachment II. Instructions for completing Attachment II are presented below.

3. Evaluation Spending (Attachment II to Part II of the Plan)

Attachment II (pp. 16-17) will present a capsule evaluation funding history for the years FY 81-83. Agencies are requested to complete columns 3 and 5 of Attachment II:

- In column 3, agencies are asked to update the figures presented in column 2.

- In column 5, agencies are requested to present estimates for FY 82. The FY 82 column (column 5) should be the sum requested in the agency evaluation plan, less expected slippage.

- Columns 3 and 5 should agree with the totals presented in Attachment I.

Agencies are also requested to revise Column 1 if it is inaccurate. Column 4 presents the FY 82 preliminary ceilings for evaluation spending for each POC. The placement of a ceiling will be necessary once again due to Congressional or Departmental action placing a ceiling on all Departmental "consultant services" spending. The ceiling may be revised based on plan review and/or action by OMB or Congress lowering the ceiling.. Column 5 will enable us to compare agency evaluation requests to the evaluation spending ceiling (column 4).

Technical assistance activities should not be reported as evaluation even though the technical assistance activities may involve evaluation.

To avoid double-counting, agencies should exclude funds transferred to the Office of the Secretary and their POC evaluation office, which will be reported by OS and the POC evaluation office.

PROJECT DESCRIPTION AND JUSTIFICATION (FY 82 FORMAT)

1. Project Title: (Title and a one-to-two-sentence description of the project.)

2. Project ID # and Type: (Provide a unique, centrally-assigned identifying number showing agency or OS staff office, fiscal year of initiation, and a three-digit number, e.g., ADAMHA-82- 001, ADAMHA-82-002, etc. State whether the project is evaluation, research, or statistics if the plan combines evaluation, research and statistical projects.)

3. Agency Proposing: (Agency and Bureau.)

4. Cost and Funding Source: (Estimated cost for prior, current, and following fiscal year and each appropriation to be used. Please note if study is a continuation.)

5. Program Evaluated: (Name the program(s) being evaluated. Use the list of HHS program names which appears in the Summer 1980 edition of User's Guide to HHS Evaluation Documentation Center or the revised program list now being prepared by ASPE and ASMB. Example: PHS-HRA-Health Resources-Health Manpower-Health Education Loans.)

6. Purpose: (Concisely present the purpose of the proposed project. In particular, what policy questions will be answered, what hypotheses will be tested, and what findings are expected from the proposed study? State whether the study is a program performance evaluation: evaluability assessment, short-term evaluation, full-scale evaluation, or program performance summary.)

7. Related Work: (Discuss related work completed, underway, or proposed which bears on the approach or expected impact of the project. Specifically indicate: (a) how the project will build on such work; and (b) how the project will provide additional information not now available to the Department. Show that no products already exist which could meet the objectives of the project by checking as appropriate, sources such as the Compendium of HEW Evaluation Studies, Summer 1980 Edition), the National Technical Information Service, other specialized information systems, and experts in other agencies.)

8. Approach/Methodology: (Describe the approach to be employed in the project. Include a discussion, whenever relevant, of the population to be examined; types of data to be examined or collected; data-gathering methods; analytic tools or techniques; and relationship of the study population to the total universe. Show that the approach proposed is likely to be adequate to support the expected results, and why it is selected over alternatives.)

9. Primary Intended Users: (Please state which one of the following descriptions best describes the primary intended users of the proposed study:

   (A) The evaluation is intended to meet the specific information needs of the HEW staff member requesting the study.

   or

   (B) The evaluation is intended to meet the information needs of the program managers and policy-makers responsible for the program being evaluated in order to improve the efficiency/effectiveness of that program.

   or

   (C) The evaluation is intended to meet information needs of a wider audience (e.g., Congress, OMB, state and local governments, the public) involved in debate on a specific policy issue. If (C), please specify the policy issue to be addressed and intended audience for the study.

   or

   (D) The evaluation is intended to meet some other information need. If (D), please specify the information need to be met.

10. Application and Utilization of Findings: (Briefly describe the actions expected to be taken on the basis of the proposed evaluation study. Show that the intended uses of the study are important and significant enough to the Department to justify the project costs. Present plans for dissemination and utilization of the final product.)

11. Date Project Description Prepared: (Indicate if revision.)

12. Execution: (Indicate whether contract, grant, or in-house. Provide rationale for not doing project in-house if project is to be done under contract. Indicate the agency and bureau under which the project will be administered, start/end dates, phases or milestones, and end products.)

13. Project Monitor/Contact: (Name, office, address, and telephone number of the person responsible for developing work statement.)

14. Individual Requesting Project: (Name person making initial request for project, or otherwise state origin of the project. State whether this project was mandated either by Congress or by the Secretary and cite the specific request.)

15. Coordination: (Identify the persons in your agency or other agencies who have reviewed the project. Also name persons who will review the project. If the project was approved in FY 1981 but not initiated in FY 1981, so state.)

16. Information Collection Burden: In order to facilitate preparation of the Department's "Information Collection Budget" as required by Executive Order 12174 and OMB's implementing procedures, indicate whether or not the project involves collection of identical data from 10 or more persons in fiscal years 1981, 1982, or 1983. If it does, provide:

(a)	OMB Forms and Number	(For projects with existing OMB numbers, provide the title and number of each form. Enter "NA" for all new FY 82 projects and others which have no OMB number.)
(b)	Purpose	(Enter "E" for Evaluation, "S" for Statistics, and "R" for Research.)
(c)	Respondent type	(Enter "I" for individuals or households, "B" for business firms, or "G" for government agencies. For all studies which examine "clients served" or "client impact," state whether or not the data to be collected will include race, ethnicity, sex, age, or handicapped status of those served.)

(d)	Whether Voluntary	(Enter "V" for voluntary, "R" for required to obtain benefit, or "M" for mandatory by statute.)
(e)	Number of Respondents	(Enter estimated number of respondents for fiscal years 1981, 1982, and 1983.)
(f)	Average Hours	(Enter estimated time required by average respondent for each fiscal year.)
(g)	Total Hours	(Enter estimated total information collection burden, (e) times (f), for each fiscal year.)
(h)	Frequency of Response	(Enter "S" for single-time and "R" for repetitive.)
(i)	Start/end dates	(Enter approximate dates, month and year in which data collection will begin and end, e.g., 3/82-5/82.)

ATTACHMENT I TO PART II OF THE PLAN

Recently Completed, On-going, and Proposed Evaluation Projects

Agency/Bureau _____

Project ID Number, Title Of Project	Actual/ Estimated Completion Date	Funding Level (Obligations in thousands) Prior Years	FY 81	FY 82	FY 83	Contract Total
a. Projects active in FY 81:						
o _____						
o _____						
o _____						
o _____						
o Other FY 81 obligations (Computer Support, S&E, etc.)	NA	NA		NA	NA	NA
b. Projects to be initiated in FY 82:						
o _____		NA	NA			
o _____		NA	NA			
o _____		NA	NA			
o _____		NA	NA			
o Other proposed FY 82 obligations (Computer Support, S&E, etc.)	NA	NA	NA		NA	NA
o Funds reserved for projects not yet identified	NA	NA	NA		NA	NA
c. Projects to be initiated in FY 83:						
o _____		NA	NA	NA		
o _____		NA	NA	NA		
o Other proposed FY 83 obligations (Computer Support, S&E, ect.)	NA	NA	NA	NA		NA
o Funds reserved for contracts not yet identified.	NA	NA	NA	NA		NA
Subtotal	NA	NA				NA
Less expected slippage in FY 81 and 82	NA		NA			NA
TOTAL SPENDING	NA	NA				NA

ATTACHMENT II TO PART II OF THE PLAN

Evaluation Spending Format
(Dollars in Millions)

Agency	(1) Actual FY 80	(2) FY 81 Ceiling	(3) Revised FY 81 Estimate*	(4) Preliminary FY 82 Ceiling**	(5) Agency FY 82 Request*
Office of Human Development Services					
Administration on Aging	$ 1.0	$ 2.1		$ 2.1	
Administration for Children, Youth, and Families	3.8	4.2		4.2	
Administration for Native Americans	.6	.2		.2	
Administration for Developmental Disabilities	-	.6		.6	
Office of Policy Development	-	.5		.5	
Office of Program Coordination and Review	1	1		.1	
SUBTOTAL	5.5	7.7		7.7	
Health Care Financing Administration					
Office of Policy Planning and Research	1.2	3.0		3.0	
Other HCFA	-	-		-	
SUBTOTAL	1.2	3.0		3.0	
Social Security Administration					
Office of Research and Statistics	1.0	2.0		2.0	
Other SSA	-	-		-	
SUBTOTAL	1.0	2.0		2.0	

* These columns are to be completed by each agency.

** Agencies should use this figure for planning purposes. Based on the merits of proposed projects, the preliminary ceiling may be raised or lowered. Revised FY 82 ceilings will be issued in September 1981.

ATTACHMENT II TO PART II OF THE PLAN (CONTINUED)

Agency	(1) Actual FY 80	(2) FY 81 Ceiling	(3) Revised FY 81 Estimate*	(4) Preliminary FY 82 Ceiling**	(5) Agency FY 82 Request*
Public Health Service					
Office of the Assistant Secretary for Health	4.2	5.2		5.2	
Health Resources Administration	3.6	3.0		3.0	
Health Services Administration	2.0	4.0***		4.0***	
Alcohol, Drug Abuse, and Mental Health Administration	2.2	3.0		3.0	
Center for Disease Control	.8	1.2		1.2	
National Institutes of Health	4.4	5.0		5.0	
Food and Drug Administration	.6	.6		.6	
SUBTOTAL	17.8	22.0		22.0	
Office of the Secretary					
Office of the Assistant Secretary for Planning and Evaluation	8.0	11.0		11.0	
Office for Civil Rights	.5	.5		.5	
Inspector General (Service Delivery Assessments)	.5	.3		.3	
Office of Refugee Resettlement	-	.5		.5	
SUBTOTAL	9.0	12.3		12.3	
DEPARTMENT TOTALS	$ 34.5	$ 46.0***		$ 46.0***	

* These columns are to be completed by each agency.

** Agencies should use this figure for planning purposes. Based on the merits of proposed projects, the preliminary ceiling may be raised or lowered. Revised FY 81 ceiling will be issued in September 1981.

*** Includes non-HEW appropriations not subject to Congressional consultant services ceiling but subject to OMB ceiling.

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